EXHIBIT 21

Whitelaw Compliance Group, LLC.

Examination of Compliance Standards for Opioid Manufacturers and Distributors

Prepared For	Prepared By
UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION *IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION* Case No. 18-OP-45132 (N.D. Ohio) MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster	Dr. Seth B. Whitelaw President & CEO Whitelaw Compliance Group, LLC. April 15, 2019

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PART I: Qualifications, Scope & Methodology

1 Qualifications

For the past 30 years, I have worked in the life sciences industry as a food and drug attorney, compliance officer, compliance consultant and professor. In addition to my J.D., I have an LL.M. in Administrative Law and an S.J.D. in Health Law. Consequently, I have extensive experience working with and interpreting legislation, statutes, regulations and guidance documents.

Since 1993, I have designed, built, and run four separate corporate compliance programs for both pharmaceutical and medical device manufacturers (C.R. Bard, Inc., SmithKline Beecham Pharmaceuticals NA, GlaxoSmithKline R&D, Misonix, Inc.). I also teach monitoring and auditing to law students and working professionals, who are enrolled in Mitchell Hamline School of Law's Healthcare Compliance Certificate program.

As a consultant for Deloitte and now my own firm, I have assessed the effectiveness of numerous U.S. and international compliance programs and their ability to detect and prevent violations of the various legal, regulatory and industry standards that govern life science company operations. In addition to assessing or developing the full compliance program, I have assessed and helped develop controls in numerous discrete areas including, but not limited to:

- pharmaceutical sampling,
- payments to and services from healthcare professionals ("HCPs"),
- product diversion controls ("grey market"),
- laboratory controlled substances controls,
- promotional material claims and use,

- third-party qualification, contracting and use, and
- medical affairs unsolicited request systems.

As an in-house compliance officer, I have conducted many audits and internal investigations directed at uncovering specific misconduct by individuals at all levels of the organization. These investigations have involved sample diversion, product diversion, clinical trial fraud, bribery and corruption, theft and misuse of human biospecimens, and the falsification of domestic and international regulatory documents (submissions, reports, certifications, licenses, import/export documents, etc.).

None of the organizations reviewed in this report have employed me or engaged the services of me and my firm. For my services on this project, I am billing $400 per hour. My compensation is not dependent on my testimony or on the outcome of this case. All my opinions offered in this report are offered to a reasonable degree of certainty. Also, I reserve the right to modify or supplement my conclusions as additional information becomes available to me, or as I perform further analyses.

2 Scope & Methodology

2.1 Scope

As an expert in the design, implementation, and operation of compliance programs in the life science industry, I was retained to examine, review and discuss:

1. The relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry.[1]
2. The application of those standards to manufacturers and distributors[2] of controlled substances.
3. The effectiveness of the compliance programs for five distributors and one manufacturer of prescription opioid medicinal products based upon available documentation from 1996 to 2018 (“review period”).

[1] The term pharmaceutical industry is used to encompass both pharmaceutical manufacturers (“marketing defendants”) and the distributors of finished pharmaceutical products to physicians, hospitals, clinics and pharmacies (“distributor defendants”).

[2] Within the pharmaceutical supply chain from manufacturer to patient, pharmaceutical distributors occupy the mid-point of the chain. Thus, at the most basic level, distributors handle the logistics of getting medicinal products from the manufacturers to the local pharmacies (including hospitals and clinics) that dispense or fill the patient’s prescription obtained from a licensed prescriber (doctor, dentist, nurse practitioner, physician’s assistant, etc.).

2.2 Methodology

The manufacturers and distributors of opioids (listed as Schedule II or III controlled substances) reviewed in this report can be further categorized into groups by the type of business model. As a result, there are three different groups reviewed in this report.

- Group 1 ("G1") distributors have a standard, "pure" distribution business model, which only involves distributing pharmaceutical products and providing other ancillary data and logistical services (not in the scope of this review). These distributors, McKesson, Cardinal Health and AmerisourceBergen, also are known as the "Big Three."
- The Group 2 ("G2") distributors have a standard business model that involves embedding distribution operations within a large, national pharmacy chain that supplied only its own pharmacies with opioid products. This group of distributors also utilize the G1 distributors to ensure an uninterrupted supply of opioids to their pharmacies or to handle Schedule II controlled substances. The G2 distributors examined are CVS and Walgreens.
- The Manufacturer Group produce the finished opioid products and typically sell in bulk quantities to the G1 distributors to supply retail pharmacy outlets. Mallinckrodt was sole member of this group.

Based on my experience and expertise outlined above, I can fairly evaluate the compliance controls employed by manufacturers and distributors and render opinions on whether they are aligned with regulatory requirements, expectations and leading industry practices, as well as whether they can be considered effective. My approach to this review utilized the same methodology I have used during the last 30 years when auditing or investigating compliance issues.

For all three groups in order to gain an understanding of each company's corporate compliance and anti-diversion programs during the review period, I conducted a detailed examination of both publicly available statements and documents, and documents produced by the manufacturers and distributors in the course of this case. In the course of preparing this report, that information included, but was not limited to:

- company websites and press releases;
- government enforcement settlement documents, including inspection reports, Memoranda of Agreement;
- government correspondence to and from the company;
- company policies and procedures;
- organization charts;
- reports of compliance breaches and investigations;
- compliance training materials;
- committee reports and presentation materials;
- audit and other internal review reports; and
- third party consultant reports.

That information examined was then evaluated against the standards described in Part II of this report.

I also examined relevant data showing opioid shipments as well as suspicious orders reported to the DEA by the distributors and manufacturers during the review period. This data pertained not only to Summit and Cuyahoga

Counties, but also other jurisdictions as well such as West Virginia. Although Summit and Cuyahoga Counties are the primary focus of this report, these anti-diversion programs were national programs and not state or county specific. Therefore, I have reviewed and evaluated activity that also occurred outside of Summit and Cuyahoga Counties. This is the same approach taken by the House Energy and Commerce Committee in its 2018 report.[3]

Finally, I also consulted with James Rafalski, a retired DEA diversion investigator, who also is an expert in this case. I discussed with him how the DEA applies the Controlled Substances Act, the accompanying regulations and the Agency's guidance when inspecting the controlled substances anti-diversion efforts of a manufacturer or a distributor, including their suspicious order monitoring programs. We also discussed what the DEA generally considers to constitute an effective controlled substances compliance program for a prudent registrant.

PART II: Compliance Program Standards

3 Understanding the Context

This part of the report discusses the compliance standards that pertain to the marketing, sale, and distribution of prescription opioid products. Although the focus of this report is on prescription opioid products, and with good reason given the current public health crisis,[4] most of the applicable compliance programs standards are not opioid specific. Likewise, these standards are publicly available and routinely accessed by compliance

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[3] *See* U.S. House Energy & Commerce Committee Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, 115th Cong., 9 (Dec. 19, 2018) (While focused on a narrow part of West Virginia, the report raises grave concerns about practices by the distributors and the DEA nationwide.) ["W.Va. Red Flags Report"].

[4] *See* Discussion *infra* at Appendix A, Figure 1.

professionals in the pharmaceutical industry to evaluate and develop industry-specific corporate and controlled substances compliance programs.

3.1 General Overview of Compliance

Within the pharmaceutical industry, the term "compliance" is used to describe a vast array of functions and activities. For example, there is "Quality Compliance," "Regulatory or FDA Compliance," controlled substances compliance (a.k.a. "Suspicious Order Monitoring" or "SOM") and others. However they are described, these functions are focused on integrating into a company's business fabric, values and principles, as well as societal expectations expressed through laws, regulations, and industry standards of conduct.[5] Therefore, compliance is not simply focused on legal and regulatory compliance to create an organizational framework to detect and prevent illegal or unethical conduct, but with establishing and promoting a corporate culture that manages risk, protects the company's reputation, and above all strives to do no harm (*primum non nocere*). This is the true essence of "compliance."

A primary function of the corporate compliance (a.k.a. "Big C Compliance") program is oversight and coordination of the other internal compliance functions to minimize duplication, together with providing an organization's Board of Directors and senior management a contextualized picture of the organization's compliance posture at a given moment of time, which highlights areas where the organization's behavior can improve.

This case concerns compliance standards for the marketing, sale, and distribution of prescription opioid products. While all prescription products carry some degree of risk, prescription opioid products, even when used for legitimate medicinal purposes, pose a special level of risk given their propensity to cause harm through addiction and the risk of diversion into the "black market" of illegal drugs.

This is evidenced by the fact that not only do prescription opioids require a prescription from a licensed medical professional, but they also have additional government-imposed controls surrounding the distribution and dispensing of these products. Therefore, it is expected that any company involved in the marketing, sale, or distribution of these products maintains a robust and effective compliance function in accordance with values, principles and societal expectations that strive to do no harm by ensuring these products are obtainable by legitimate patients while maintaining efforts to detect and prevent illegal diversion. As an ancillary benefit, such efforts can reduce the company's exposure to legal and reputational risk helping the company fulfill its "contract" with shareholders to protect their investments and maintain confidence in the company.

This expectation to maintain a robust and effective compliance program is true even if there were no laws or regulations governing the marketing, sale, and distribution of prescription opioid products (e.g., the Controlled Substances Act). It also is an important "compliance" consideration that laws and regulations constitute the "floor" and not the "ceiling" of expected conduct. In other words, laws and regulations establish the bare minimum requirements that companies must abide by, but good companies, especially those that understand the

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[5] *See, e.g.* Brent Saunders, Our Social Contract with Patients, Allergan CEO Blog (Sep. 6, 2016), https://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients.aspx. Brent Saunders, current CEO of Allergan Plc and a former Compliance Officer for Schering-Plough Corporation wrote "[t]he health care industry has had a long-standing unwritten social contract with patients, physicians, policy makers and the public at large."

value of compliance, can and often do go farther.

The specific governing standards for what constitute effective compliance programs for the pharmaceutical industry are derived largely from four source categories. These are (1) state and federal statutes, plus any accompanying regulations, (2) government guidance documents, (3) industry enforcement settlements, and (4) voluntary industry standards including codes of conduct or ethics. Compliance professionals use these categories to develop compliance programs in the pharmaceutical industry that manage legal, regulatory and reputational risks effectively.

Finally, it is important to keep in mind that the origins of both controlled substances and corporate compliance programs predate the start of the report's review period (i.e., 1996).

3.2 The Interlocking Relationship between Suspicious Order Monitoring, Controlled Substances, and Corporate Compliance Programs

A suspicious order monitoring or SOM program is a subset of the wider universe of controls necessary for a distributor to meet its overall obligation to maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[6] As discussed in greater detail below, that wider universe of controlled substances diversion controls is itself a subset of the universe of controls a distributor needs to meet its ability to exercise due diligence to prevent and detect inappropriate and potentially criminal conduct and to promote otherwise an organizational culture that encourages ethical conduct (a.k.a. a corporate compliance program). The figure below illustrates that the relationship between SOM, a full controlled substances program and the enterprise-wide corporate compliance program resembles a set of Russian nesting dolls.

[6] *See* 21 U.S.C. §§ 823 (b)(1). The Uniform Controlled Substances Act of 1994 states that "'diversion' means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use." *See* National Conference of Commissioners on Uniform State Laws, *Uniform Controlled Substances Act (1994)*, § 309(a) (Dec. 28, 1995) at http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf.

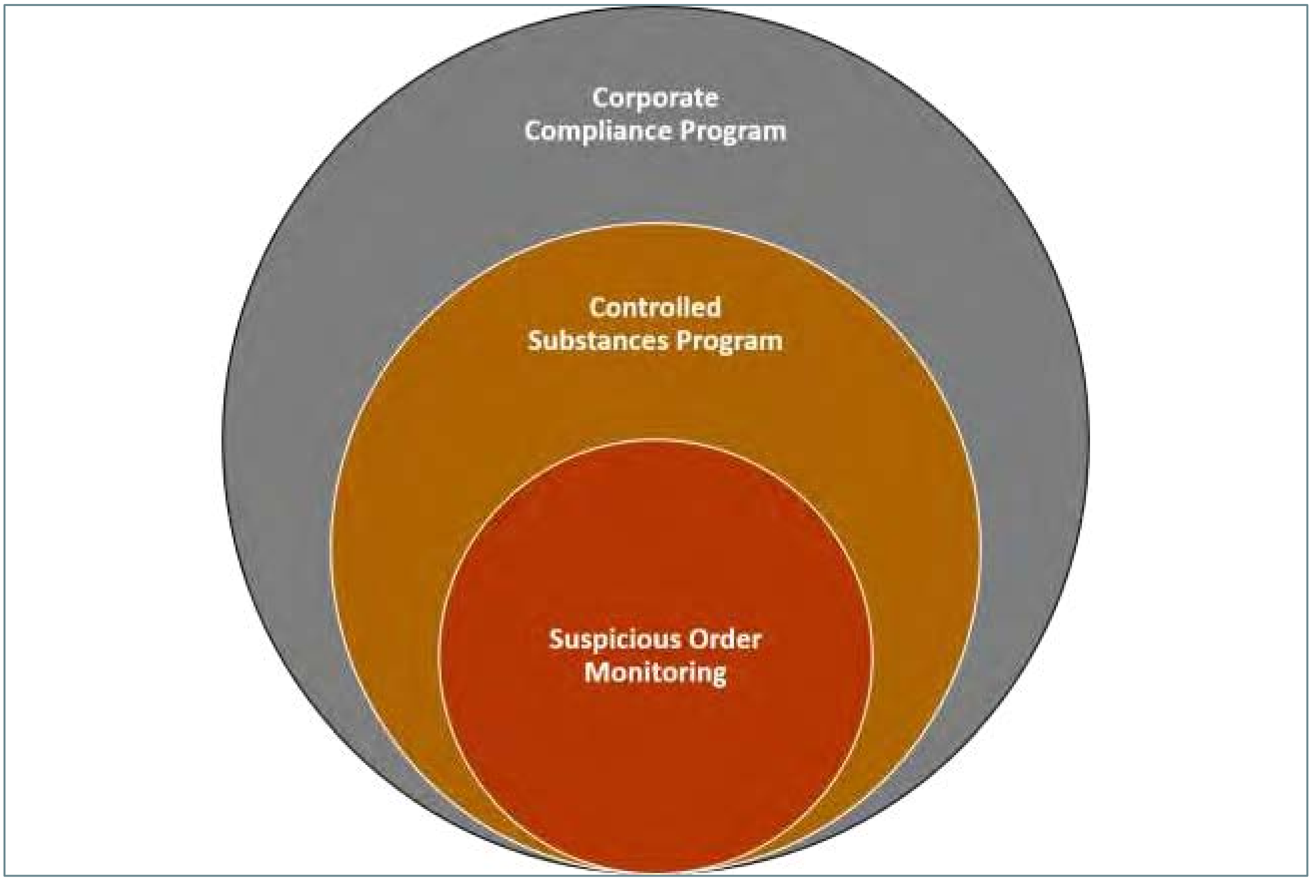

Figure 1: Relationship Between SOM, Controlled Substances & Corporate Compliance

As a result of this interlocking or "nested" arrangement, for a compliance program at any of the levels to be considered effective its basic building blocks must address the Seven, now Eight, Elements of an Effective Compliance Program.

4 Compliance Standards for Corporate Compliance Programs (1991 to the Present)

4.1 Federal Sentencing Guidelines for Organizations

In 1991, twenty years after passage of the CSA, the modern corporate compliance program was born with the publication of the first version of the Federal Sentencing Guidelines for Organizations ("FSGs"). Established by the U.S. Sentencing Commission ("Sentencing Commission"), the Guidelines are a "mechanical structure [that] determines an appropriate monetary fine through means of a mathematical formula: assigning a dollar figure to the seriousness of the offense and multiplying that number by a figure representing the culpability level of the

organization."[7] Consequently, "[t]he Guidelines' drafters intend[ed] to influence corporate behavior – both before and after wrongdoing occurs – by providing various adjustments to the determination of the seriousness of the offense and of the organization's culpability."[8]

Applying a "carrot and stick approach," the Sentencing Commission gave organizations an incentive to implement an effective compliance program. Therefore, the FSGs:

> not only encourage corporations to exemplify "good corporate citizenship," but [they] also provide a means to "rehabilitate' corporations that have engaged in criminal conduct ….[9]

According to the FSGs, "[t]he hallmark of an effective [compliance] program to prevent and detect violations of law is that the organization exercises due diligence in seeking to prevent and detect criminal conduct by its employees and other agents."[10] The Sentencing Commission, in a comment to the applications section, outlined seven criteria for establishing an effective compliance program. Commonly referred to as the "Seven Elements," the FSGs required that for a compliance program to qualify as "effective" and receive mitigation credits:[11]

1. The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct;
2. Specific individual(s) within the high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures;
3. The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew or should have known through the exercise of due diligence, had a propensity to engage in illegal activities;
4. The organization must have taken steps to communicate its standards and procedures effectively to all employees and other agents, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required;
5. The organization must have taken reasonable steps to achieve compliance with its standards, by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution;

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[7] *See* Lawrence Finder and A. Michael Warnecke, *Overview of The Federal Sentencing Guidelines for Organizations and corporate Compliance Programs,* 1, ABA Criminal Justice Section (Apr. 12, 2005) at https://www.americanbar.org/content/dam/aba/publishing/criminal_justice_section_newsletter/crimjust_wcc_OVERVIEW_OF_THE_FEDERAL_SENTENCING_GUIDELINES_FOR_ORGANIZATIONS_AND_CORPORATE.authcheckdam.pdf.

[8] *Id.*

[9] *See* Diane Murphy, *The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics*, 87 IOWA L. REV. 697, 703 (2002) (citations omitted)

[10] *See id.* (Quoting from the U.S. Sentencing Guidelines Manual at ch. 8).

[11] *See* U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991).

6. The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, the discipline of individuals responsible for the failure to detect an offense. The adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific; and
7. After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses -- including any necessary modifications to its program to prevent and detect violations of law.

These general elements outlined in the Sentencing Guidelines are not pharmaceutical-specific but rather apply to corporations across all industries. As the Sentencing Commission noted in its commentary, "[t]he precise actions necessary for an effective program to prevent and detect violations of law will depend upon a number of factors" including, but not limited to the size of the organization, the fact that via the nature of the business certain types of offenses are more likely to occur, and the organization's prior history.[12] Therefore, it is incumbent upon each corporation to implement the elements in a way that effectively addresses and mitigates the risks in their specific industry and for their individual company.

From their origin in 1991 through 2010, the Seven Elements were not legally or regulatorily mandated. Nevertheless, after the case of *U.S. v. C.R. Bard, Inc.* in 1994,[13] many of the larger pharmaceutical companies and other health care organizations began voluntarily implementing the Seven Elements with an understanding that the elements established the foundation for determining the worthiness of their compliance efforts and programs.

During this initial phase, the focus of industry activity and government enforcement actions was largely confined to establishing the role of the compliance officer and instituting the basic compliance framework outlined by the Federal Sentencing Guidelines.[14] The baseline requirements of a compliance program in this era typically involved:

1. Hiring a compliance officer and establishing a compliance committee;
2. Developing written compliance standards and policies;
3. Implementing an employee training program;
4. Establishing a confidential disclosure program (e.g., hotline);
5. Restricting the employment of ineligible persons (e.g., pre-employment screening); and
6. For companies under a plea agreement, providing implementation and annual reports to OIG on the status of the entity's compliance activities.[15]

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[12] *See id.*

[13] 848 F. Supp. 287 (D. Mass. 1994).

[14] *Id.* Although *Bard* was an FDA enforcement action against a medical device company, the settlement, which required the company to develop and implement a compliance program, helped motivate the pharmaceutical industry to make corporate compliance a priority.

[15] These baseline requirements were later expanded in 2001 with the TAP Pharmaceuticals Corporate Integrity Agreement. *See generally,* Corporate Integrity Agreement between DHHS OIG and TAP Pharmaceutical Products, Inc., https://www.oig hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf (2001). The TAP CIA saw the introduction of the Compliance Committee and the independent review organization ("IRO") to conduct annual reviews, as well as the

In 2004, the Federal Sentencing Commission significantly updated the Sentencing Guidelines. The corporate compliance program section was improved and expanded clearly signaling the importance of corporate compliance programs. Perhaps most importantly, the Sentencing Commission elevated the corporate compliance discussion from a comment to its own new chapter and section.[16] The Commission also made three other major changes.

First, with the addition of "ethics" to the program name, the Sentencing Commission signaled that these programs have an expanded role beyond just detecting and preventing criminal conduct. As of 2004, an effective ethics and compliance program was intended to promote "an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[17]

Second, the Seven Elements were expanded to include an eighth element – risk assessment. Although listed explicitly for the first time, the risk assessment element was implied in the original 1991 Guidelines comment.[18] With the 2004 changes, the section explicitly highlighted it stating:

> In implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.[19]

Third, the Sentencing Commission explicitly articulated that courts and judges could apply industry practice and standards in government regulations when concluding whether a compliance program was effective, and the failure to take governmental guidance and industry standards into account was viewed as a negative.

Specifically, the Commission wrote:

> (A) **In General.**—Each of the requirements set forth in this guideline shall be met by an organization; however, in determining what specific actions are necessary to meet those requirements, factors that shall be considered include: (i) applicable industry practice or the standards called for by any applicable governmental regulation; (ii) the size of the organization; and (iii) similar misconduct.
>
> (B) **Applicable Governmental Regulation and Industry Practice.** —An organization's failure

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requirement to make self-disclosures to the OIG of overpayments, investigations, legal proceedings, and other "reportable events" defined by the agreement. That settlement also introduced the conjoined concepts of the "covered person" and "certain covered persons" targeting various groups of employees for additional scrutiny and training. Now, instead of just one class of employees requiring training, the TAP CIA, and its progeny, required companies to identify those employees who constituted "covered persons or "certain covered persons" and establish and track training programs, as well as certifications, tailored specifically to each group.

[16] *See* U.S. Sentencing Commission, *Guidelines Manual*, § 8B.2.1 (Nov. 2004) ["FSGs 2004"]. Section 8B.2.1 was amended in 2010, 2011 and 2013, however, those amendments were technical in nature and did not affect the overall requirements set out in that section. *See* U.S. Sentencing Commission, *Guidelines Manual*, Appendix C and Supplement to Appendix C (Nov. 2018) (Amendments 744, 758 and 778). Therefore, the 2004 Sentencing Guidelines contain the last major substantive update to the compliance program section.

[17] *See id.* at § 8B.2.1(a)(2).

[18] Although this concept was noted in the 1991 version, it was the very last sentence of the comment. *See* U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991).

[19] *Id.* at § 8B.2.1(c).

to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective compliance and ethics program.[20]

4.2 OIG Compliance Program Guidance

From 1998 to 2008, the Office of Inspector General ("OIG") for Health and Human Services issued a series of compliance program guidance documents that pertained to a wide variety of healthcare organizations and companies including hospitals, home health agencies and clinical laboratories in 1998[21], durable medical equipment, and hospices in 1999[22], pharmaceutical manufacturers in 2003[23] and nursing facilities in 2008.[24] According to the OIG, '[t]he purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements."[25] Each guidance followed a standard pattern of discussing the elements of an effective compliance program, as articulated by the Sentencing Guidelines, in the context of that particular industry segment. The compliance program guidance also represented the OIG's position on what constituted leading practices at that time for that industry segment.

Although the OIG never established specific compliance program guidance for pharmaceutical distributors, a close reading of the guidance published in 2003 for pharmaceutical manufacturers provides many informative insights suitable for distributors as well. In fact, the OIG noted that the information contained in the Guidance might be useful to other groups beyond just pharmaceutical manufacturers:

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[20] *See* FSGs 2004. at § 8B.2.1, comment. (n. 2) (emphasis added). In 2005, the U.S. Supreme Court in a complex opinion concluded that the Sentencing Guidelines violated a defendant's Sixth Amendment right to a jury, but also found that courts could still use them, provided the court was able to tailor the final sentencing to address the specific facts of the case. *See* Finder at 2 (Discussing *United States v. Booker*, 123 S. Ct. 785 (2005)). The DOJ in response issued a memorandum to all federal prosecutors instructing them that they are required to use the Sentencing Guidelines and ranges in all but the extraordinary case. *See* Memorandum from James B. Comey, Dep. Atty. Gen. To All Fed. Prosecutors, *Department Policies and Procedures Concerning Sentencing* (Jan. 28, 2005), available at http://sentencing.typepad.com/sentencing_law_and_policy/files/dag_jan_28_comey_memo_on_booker.pdf. The net result is that despite *Booker's* holding, the Sentencing Guidelines continue to define the elements of an effective ethics and compliance program by the courts, the regulators and the life sciences industry, and the passage of the Affordable Care Act in 2010 (see below) has eroded *Booker*'s relevance even further.

[21] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998); OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42410 (Aug. 7, 1998); OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076 (Aug. 24, 1998). All OIG Compliance Guidance documents are available at https://www.oig hhs.gov/compliance/compliance-guidance/index.asp. To date, the OIG has published no specific compliance program guidance document for distributors.

[22] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry, 64 Fed. Reg. 36368 (Jul. 6, 1999); OIG Compliance Program Guidance for Hospices, 64 Fed. Reg. 54031 (Oct. 5, 1999).

[23] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Pharma Guidance").

[24] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42410 (Aug. 7, 1998).

[25] *See* OIG Pharma Guidance at 23731.

> In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs.[26]

As experienced compliance professionals know, any compliance program guidance does not necessarily need to be written for the specific industry segment to contain pertinent insights on what constitutes effective compliance.

4.3 Affordable Care Act

Perhaps the most significant change for corporate compliance programs occurred with the passage of the Affordable Care Act ("ACA") in 2010.[27] As noted previously, the standards detailing what constitutes the make-up of an effective compliance program have existed since 1991 and were widely adopted by most large pharmaceutical manufacturers and other prudent life sciences companies. They also were incorporated in various government guidance documents and settlement agreements. However, the passage of the ACA now made having a corporate compliance program a requirement to be eligible to participate in and receive reimbursement from federal health care programs.

Under ACA section 6401(a)(7) in order to participate in the Medicare program (e.g., receive reimbursement) after an implementation date determined by the Secretary of HHS:

> a provider of medical or other ***items or services or supplier*** within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.[28]

The same requirement also was applied to participants in state Medicaid programs, as well as the Children's Health Insurance Program ("CHIP").[29]

Congress used the concept of "core elements" to tie the previous corporate compliance guidance and standards into this new requirement by stating:

> The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.[30]

Congress also was specific regarding the Secretary's implementation determination that:

[26] *See* OIG Pharma Guidance at 23742, n.5.

[27] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6401(a)(7), 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G) (2010) [hereinafter cited as ACA]

[28] *Id.* at § 6401(a)(7)(A) (Emphasis added).

[29] *Id.* at § 6401(b)(5) and (c)(2).

[30] *Id.* at § 6401(a)(7)(B).

> The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. **The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.**[31]

4.4 DOJ & OIG Program Effectiveness Guidance

In 2017, both the OIG and DOJ published guidance on the elements that they consider when determining whether a corporate compliance program is effective.[32] However, "[b]oth sets of guidance emphasize that they are not a 'checklist to be applied wholesale to assess a compliance program' but rather are lists of common elements to be considered when "making an individualized determination."[33] In addition, while there are similarities between the two guidance documents, there also some significant differences starting with the format. The DOJ guidance is formulated as questions to be considered, while the OIG document examines things to measure and how to accomplish those measurements.

5 Compliance Standards for Controlled Substances (1970 – the Present)

5.1 Controlled Substances Act

The origins of effective compliance programs for controlled substances (a.k.a. anti-diversion programs) are traceable to the enactment of both the Controlled Substances Act ("CSA"), which is the primary statute governing the manufacture and distribution of controlled substances, and the Drug Enforcement Administration's ("DEA") implementing regulations.[34] Originally enacted in 1970, the CSA established the classification system for controlled substances (Schedules I-V), as well as general controls that pertain to each

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[31] *Id.* at § 6401(a)(7)(C) (Emphasis added). As of the date of this report, the Secretary has not issued a formal determination of "core elements" under subparagraph (B) or the implementation date under subparagraph (C). However, given the existence of the Federal Sentencing Guidelines, the OIG Compliance Program Guidance in 2003 and the most recent OIG and DOJ guidance documents on program effectiveness issued in 2017, I believe the pragmatic compliance reading is that the "core elements" and timing requirements have been satisfied. Consequently, as of 2010, any pharmaceutical distributor, which receives federal healthcare dollars either directly or indirectly, must have an effective corporate compliance program that addresses the risks in a particular industry or industry category.

[32] *See* U.S. Department of Justice, Criminal Division- Fraud Section, "Evaluation of Corporate Compliance Programs," https://www.justice.gov/criminal-fraud/page/file/937501/download; *see also* HCCA-OIG Compliance Effectiveness Roundtable, Measuring *Compliance Program Effectiveness: A Resource Guide* (Mar. 27, 2017) ("On January 17, 2017 a group of compliance professionals and staff from the Department of Health and Human Services, Office of Inspector General (OIG) met to discuss ways to measure effectiveness of compliance programs."), available at https://oig hhs. gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf.

[33] *See* S. Foroughi and K. Wildoner, *Effectiveness, The Holy Grail of Compliance - Both the DOJ & OIG Weigh In*, 3.7 LIFE SCIENCE COMPLIANCE UPDATE 7, 14 (Jul. 2017) (citations omitted), available at https://complianceupdate.policymed.com.

[34] *See* 21 U.S.C. § 801 *et seq., see also* 36 Fed. Reg. 7778 (Apr. 24, 1971) codified at 21 C.F.R. part 1301.

schedule.[35] Regardless of the Schedule level, the fact that a medicinal product is scheduled means that it has been determined that additional controls regarding the manufacture, distribution, dispensing and prescribing of that product are necessary to safe guard the public health.[36]

Schedule II products are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.[37] Consequently, products in this category are considered the most dangerous products that can be lawfully prescribed by a medical professional. Schedule III products are defined as drugs with a potential for abuse that is less than the drugs in Schedules I and II, with use potentially leading to moderate to low physical dependence and high psychological dependence.[38] While these products are considered less dangerous than Schedule II drugs, nevertheless, they are potent medicinal products requiring the additional controls mandated by the CSA to prevent diversion and misuse.

As a baseline, the CSA requires that all major participants in the controlled substance supply chain (manufacturers, distributors, dispensers, and prescribers) be registered, thus creating the so-called "closed loop" system.[39] It further defines the basic controls expected of both manufacturers and distributors. A critical condition for granting, and maintaining, a manufacturer's or distributor's registration is the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[40] The failure of any registrant to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required" by the Act is a criminal offense.[41]

Although the CSA has been amended several times since 1970, this basic requirement to maintain effective diversion controls has remained untouched.[42] Therefore, when the manufacturers and distributors developed the governing standards of conduct to detect and prevent diversion of prescription opioids, it was incumbent on

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[35] *See* 21 U.S.C. §§ 812(b)(2), (b)(3) and (c). The CSA defines an opioid as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." *See* 21 U.S.C. § 802(18). For purposes of this review the focus is opioid products, which are classified as Schedule II or III controlled substances.

[36] *See, e.g.,* U.S. DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT AGENCY, 96-2 DIVERSION INVESTIGATOR'S MANUAL, § 5126 (Apr. 16, 1996), CAH_MDL_02203357.

[37] *See* 21 U.S.C. § 812(b)(2).

[38] *See* 21 U.S.C. § 812(b)(3).

[39] *See* 21 U.S.C. § 823.

[40] *See* 21 U.S.C. §§ 823 (a)(1) and (b)(1) (Governing manufacturers and distributors respectively). As a threshold matter, the CSA does not specifically define "diversion." However, the language "into other than legitimate medical, scientific, and industrial channels" infers that if a controlled substance were moved into an illegitimate channel that constitutes "diversion." According to the Uniform Controlled Substances of 1994, "'diversion' means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use." *See* National Conference Of Commissioners on Uniform State Laws, *Uniform Controlled Substances Act (1994)*, § 309(a) (Dec. 28, 1995) at http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf.

[41] *See* 21 U.S.C. § 842(a)(5).

[42] *See, e.g.,* Pub. L. 91-513 available at https://www.gpo.gov/fdsys/pkg/STATUTE-84/pdf/STATUTE-84-Pg1236.pdf (Comprehensive Drug Abuse Prevention and Control Act of 1970).

each of them to consider the CSA's requirements as they developed and maintained an effective anti-diversion program.

5.2 DEA Controlled Substances Regulations

A year after passage of the CSA, the DEA in 1971 issued implementing regulations to clarify many of the CSA's important provisions including the registration and security controls for manufacturers, distributors, and dispensers of controlled substances.[43] A crucial component for controlled substances distributors was the security controls section outlining the physical security and other controls for non-practitioners.[44]

Building from the original CSA provisions, the DEA's regulations required that all non-practitioner registrants (e.g., manufactures and distributors) develop and maintain:

> effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.[45]

The types of security controls that manufacturers and distributors must employ include:[46]

- Making a good faith inquiry to determine if the person or entity receiving controlled substances is authorized to receive them;
- Maintaining a system to detect and disclose suspicious orders (a.k.a. Suspicious Order Monitoring or SOM);
- Notifying the DEA of thefts or significant losses; and
- Ensuring that any common carriers used in the supply chain have adequate security measures to prevent losses.

As laid out by the DEA regulations, a manufacturer's and distributor's SOM program must meet a relatively short list of requirements:

- There must be a system designed and operated to disclose suspicious orders of controlled substances.
- The distributor must inform the local DEA Field Office when the distributor discovers a suspicious order.
- At a minimum, orders are deemed suspicious if they are (a) of unusual size, (b) deviate substantially from a normal pattern, or (c) of unusual frequency.[47]

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[43] *See* 36 Fed. Reg. 7778 (Apr. 24, 1971) codified at 21 C.F.R. part 1301.

[44] *See* 21 C.F.R. §§ 1301.72 and 1301.74.

[45] *Id.* at § 1301.71(a).

[46] *See id.* at 1301.74.

[47] *See* 21 C.F.R. § 1301.74(b); *see also Masters Pharmaceuticals, Inc. v. DEA*, 15-1335 (D.C. Cir. 2017) (upholding DEA's interpretations of its regulations relative to defining a suspicious order and the timing of reporting).

Additionally, any manufacturer, which provides complimentary samples, must maintain appropriate controls for controlled substances in addition to the general controls for pharmaceutical marketing samples.[48]

Also embedded within the DEA's regulations was the important concept that effective security controls are not static.[49] The regulations expressly contemplated that security controls should be adjusted (increased or decreased) to account for changing circumstances.[50] When determining whether a registrant is in substantial compliance with the security requirements, the DEA may apply a variety of factors, including but not limited to, "[t]he adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations."[51] Therefore, as of 1971, both manufacturers and distributors were on notice that, at a minimum, they were expected to assess their controls periodically (e.g., undertake a risk assessment), as well as maintain a system to detect suspicious orders of controlled substances.

5.3 DEA Guidance on Controlled Substances

5.3.1 Controlled Substances Security Manual & Suspicious Order Task Force (1997 to 2004)

In 1991, the DEA published the Controlled Substances Security Manual as an informational guide to the CSA.[52] The manual provided a more user-friendly outline of the CSA and its accompanying regulations. Later, in November 1997, the DEA announced the formation of the Suspicious Order Task Force.[53] The task force was "responsible for providing the Attorney General with recommendations, advice, and proposals for the establishment of such guidelines that will adequately define suspicious orders of listed chemicals."[54] It was comprised of 20 members including members from "relevant industry/trade associations and state and local law enforcement agencies."[55]

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[48] *Id.* The PDMA, which is administered by the U.S. Food and Drug Administration ("FDA") governs the distribution of pharmaceutical marketing samples. FDA's regulations for the most part mirror the DEA's requiring proof of to whom the samples were delivered, reporting of significant losses, investigating losses and suspected falsification, and providing timely notification of losses to the Agency. *See* 21 C.F.R. part 203. One difference between the two regulatory schemes is that the FDA specifically mandates the manufacturer maintain written policies and procedures governing how its sample accountability systems and processes operate. *See* 21 C.F.R. § 203.34. In 2010, the ACA added section 6004 which added yet another layer to the sampling of non-scheduled pharmaceuticals moving them closer to the "closed loop" DEA system. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6004, 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G) (2010).

[49] *See, e.g.,* Letter from W. Goggin to J.M. Gray (Oct. 17, 2008) ("diversion control is not a 'one size fits all' effort), WAGMDL00673706.

[50] *Id.* at § 1301.71(c).

[51] *Id.* at § 1301.71(b)(14).

[52] *See* U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION, CONTROLLED SUBSTANCES SECURITY MANUAL (May 1991) available at http://www.cogan.com/documents/DEA_Controlled_Substances_Security_Manual.pdf.

[53] *See* 62 Fed. Reg. 61829 (Nov. 19, 1997).

[54] *Id.*

[55] *Id.*

5.3.2 The Chemical Handler's Manual

The DEA created the Chemical Handler's Manual in response to the enactment of the various chemical control laws, amending the original CSA, but also to provide general guidance on complying with the CSA.[56] Therefore, it contains relevant guidance on diversion controls and suspicious orders, including suspicious order identification criteria established by the Task Force.[57]

The Manual also outlined "a voluntary formula for use by distributors to wholesale and retail levels."[58] The formula outlined involved setting threshold purchase levels based on the last twelve months purchases by the same customer type from the same distribution center (e.g., the customer group).[59] That amount is divided by the total number of customer months (months in which purchases are above zero) and multiplied by a factor to determine the maximum amount a customer may purchase.[60] According to the Manual, the "[f]actor equals 3 for C-II and C-III Controlled Substances **containing List I Chemicals** and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products **containing List I chemical items**."[61]

While the manufacturers and distributors here utilized the Factor of 3 for setting thresholds for opioid products, the factor was based only on Schedule II and III controlled substances containing List 1 Chemicals.[62] A plain reading of Appendix E-3 is that if a Schedule II or III controlled substance does not contain a List 1 chemical, the factor is not applicable. Therefore, for opioid products not containing a List 1 chemical, that factor is not applicable. However, regardless of whether using the factor is applicable or not, the DEA manual does not indicate how a level that is 300% above the base threshold is the appropriate multiplier to use.

Independent of the type of products the Chemical Handler's Manual applies to, it is clear that the Manual does not support the practice of shipping suspicious orders after they are reported. To this point, the Chemical Handler's Manual states "when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicious. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions."[63]

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[56] *See* U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION CHEMICAL HANDLER'S MANUAL, (Jan. 2004) at https://www.justice.gov/sites/default/files/open/legacy/2014/05/09/2004-chemical-handlers-manual.pdf. ["Chemical Handlers Manual, 2004 Edition"].

[57] *Id.* at 37 (Appendix E).

[58] *Id.* at 41 (Appendix E-3).

[59] *Id.*

[60] *Id.*

[61] *Id.* (emphasis added).

[62] The Manual states that a "*List I chemical* is a chemical that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List I chemical by the DEA Administrator or Congress. Chemicals in List I generally are precursors and have been determined by DEA to require a greater level of control than other listed chemicals." *See id.* at 8 (emphasis added).

[63] *See* Chemical Handler's Manual, 2004 Edition, at 19.

5.3.3 The DEA Industry Initiative

"Recognizing that wholesale distributors played a key role in the pharmaceutical supply chain, the DEA launched an industry-specific anti-diversion initiative in 2005, called the "'Distributor Initiative Program.'"[64] According to the DEA, the goal of the initiative was to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."[65] Initially, the DEA focused the program on educating drug distributors who were supplying controlled substances to rogue Internet pharmacies and to diverting pain clinics and pharmacies.[66] Through the program, the DEA "educates distributors about their obligations under the CSA, as well as provides registrants with current trends and 'red flags' that might indicate that an order is suspicious."[67] McKesson, Cardinal Health, and Amerisource Bergen all attended sessions with the DEA.[68] The materials used in each meeting were almost identical.[69]

During those meetings, the DEA told the participants that:

1. Reporting a suspicious order to the DEA does not relieve the distributor of its responsibility to maintain effective anti-diversion controls.
2. The DEA cannot tell distributors if an order is legitimate or not.
3. Distributors, therefore, must determine which orders are suspicious and decide whether to proceed with the sale.
4. If distributors know or suspect that controlled substances are being dispensed outside the course of professional practice shipments to those customers must stop immediately.
5. The DEA may revoke a distributor's registration under public interest grounds.[70]

Although couched in terms of distributors, because the requirements for manufacturers are the same, the DEA's statements as part of this initiative would apply to them too.

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[64] *See* MEMORANDUM FROM COMMITTEE MAJORITY STAFF, H.R. COMM. ON ENERGY AND COMMERCE, SUBCMTE. ON OVERSIGHT AND INVESTIGATIONS, HEARING ENTITLED "COMBATING THE OPIOID EPIDEMIC: EXAMINING CONCERNS ABOUT DISTRIBUTION AND DIVERSION," 5, (May 4, 2018), https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-20180508-SD002.pdf.

[65] *Id.* (quoting from *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm on Energy & Commerce, Subcomm. on Health*, 113th Cong., (2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.)).

[66] *See id.*

[67] *See id.* (quoting from *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm on Energy & Commerce, Subcomm. on Health*, 113th Cong., (2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.)).

[68] *See* Memorandum to J. Rannazzisi from M. Mapes, Internet Presentation with McKesson Corp. on September 1, 2005 (Oct. 20, 2005), MCKMDL00496859; Presentation by M. Mapes and K. Wright to Cardinal Health, *Internet Pharmacy Data,* (Aug. 22, 2005), CAH_MDL2804_01457737; Presentation by M. Mapes and K. Wright to AmerisourceBergen, *Internet Pharmacy Data,* (Aug. 10, 2005), ABDCMDL00315887.

[69] *Id.*

[70] *See* Presentation by Mapes and Wright to AmerisourceBergen at ABDCMDL00315893-94, and ABDCMDL00315899.

5.3.4 DEA Letters to All Registrants (a.k.a. The Rannazzisi Letters) (2006 to 2012)

In 2006, 2007 and again in 2012, Joseph Rannazzisi, Deputy Assistant Administrator of the Office of Diversion Control also issued a series of guidance letters.[71] Known collectively as the Rannazzisi letters, they were sent to all registered manufacturers and distributors reminding them of their obligations under the CSA to prevent diversion and detect suspicious orders.[72] Beyond the general reminders and disclaimer that the DEA does not endorse a particular system or sets of controls, each letter focused on a particular implementation topic, providing DEA's current thinking about what was or was not effective.

The initial letter in September 2006 focused on a registrant's basic obligations noting that the suspicious order monitoring "requirement is in addition to, and not in lieu of, the general requirement . . . that a distributor maintains effective controls against diversion."[73] The DEA also provided a list of factors that could signal possible diversion.[74]

The focus of the February and December 2007 letters again was suspicious order monitoring. While the February 2007 letter's content was almost identical to the September 2006 letter, the December 2007 letter focused on what constituted timely reporting.[75] The December letter also cautioned registrants about placing too much reliance on rigid formulas to detect diversion, as well as the need to conduct meaningful investigations of suspicious orders.[76]

The June 2012 letter continued the discussions started in December 2007 and once more focused on suspicious order monitoring. This time the DEA expressed concerns over registrants' not making timely reports to the DEA Field Offices as the regulations require. However, the DEA commented that merely reporting suspicious orders was not enough noting:

> Registrants who routinely report suspicious orders yet fill these orders without first ascertaining that the order will not be diverted into other than legitimate medical, scientific, or industrial channels, are failing to maintain effective controls against diversion.[77]

Thus, the DEA reiterated its expectation that registrants needed to conduct meaningful due diligence <u>before</u>

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[71] *See* Letters from J. Rannazzisi to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007 and Jun. 12, 2012) ["DEA (date) Letter(s)"].

[72] *Id.*

[73] *See* DEA 9/27/2006 Letter at 2.

[74] *See Id.* at 3 (Listing circumstances that might be indicative of diversion).

[75] *See* DEA 12/27/2007 Letter; *see also* Letter from G.Thomas Gitchel to R.J. Streck (Apr. 27, 1984) ("any automated data processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler."), CAH_MDL2804_01465723. Mr. Gitchel was the DEA's Acting Chief of the Diversion Operations Section at that time.

[76] *Id.*

[77] *See* DEA 6/12/2012 Letter at 2; *see also* HDMA *Position Statement and Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances* (2008), WAGMDL00673706-WAGMDL00673722.

shipping potentially suspicious orders.[78]

5.3.5 Masters Pharmaceutical Case

While the case revoking the DEA registration for Masters Pharmaceuticals, Inc. ultimately came before the D.C. Circuit,[79] the opinion of DEA's Acting Administrator Chuck Rosenberg provides specific guidance on the determination of exactly when an order of unusual size, frequency or pattern "is discovered" as "suspicious."[80] This determination is particularly important because if a suspicious order "is discovered," the manufacturer or distributor should not ship the order to the customer.[81] Thus, as discussed throughout this report, distributors and manufacturers go to extraordinary lengths to avoid "discovering" a suspicious order.

The regulations do not expressly define what is meant by "when discovered," and as a result, manufacturers and distributors use various euphemisms, such as "orders of interest" or like terms not found in the regulation as an attempt to avoid triggering the reporting requirement. However, the general principles of statutory construction hold that words not defined by a statute or regulation should be given their "plain meaning" as derived from the dictionary.[82] Consequently, when a manual or automated threshold system "discloses" the excessive/suspicious order that constitutes "when discovered" triggering the reporting requirement.

According to Mr Rosenberg's opinion "[s]uspicion as to the existence of a circumstance (i.e., that a customer is engaged in diversion) is simply a far lower standard of proof than whether it is 'likely' that the circumstance exists … [and] does not even rise to the level of probable cause."[83] Thus, he concluded that "an order has been discovered to be suspicious and the regulation has been violated where the registrant has obtained information that an order is suspicious but then chooses to ignore that information and fails to report the order."[84]

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[78] *Id.* In same vein as Rannazzisi letters, James Arnold, Unit Chief, Regulatory Unit, DEA HQ, in June 2013, spoke about diversion controls at a conference for manufacturers, importers and exporters hosted by the DEA. *See* Presentation by James Arnold, *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conference, (Jun. 2013) available at https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/. While largely a recap of the statute and regulations, Mr. Arnold made several important points during his talk. First, he stressed that the responsibility for identify suspicious orders is the registrant's, but once identified as suspicious, the order must not be shipped. *Id.* at slide 41. Second, Mr. Arnold noted registrants must know their customers and have determined if there are any "red flags" to doing business with them. These "red flags" can include any number of factors including, but limited to, the customer's location, news reports, etc. *Id.* at slides 42 to 53.

[79] *See Masters Pharmaceutical, Inc. v. DEA*, No. 15-1335, (D.C. Cir. 2017). The D.C. Circuit's opinion is relevant because the Court affirmed the positions taken by Acting Administrator Rosenberg.

[80] *See* 80 Fed. Reg. 55418 (Sept. 15, 2015).

[81] *See* Letter from J. Rannazzisi to All Registrants (Jun. 12, 2012); *see also* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 11 (2008) (blocking "orders of interest"), WAGMDL00673706.

[82] *See, e.g., Morissette v. United States*, 342 U.S. 246, 263 (1952); *FDIC v. Meyer*, 510 U.S. 471, 476 (1994) (In the absence of a statutory definition, "we construe a statutory term in accordance with its ordinary or natural meaning."); *see also* LARRY M. EIG, CONG. RESEARCH SERVICE, 97-589, STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS, 5-8 (2014).

[83] *See* 80 Fed. Reg at 55478.

[84] *Id.*

With regards to the "when discovered" provision, Mr. Rosenberg concluded the provision is intended "'to prevent manufacturers and distributors from simply filing "daily, weekly, or monthly" suspicious order reports'" because "'periodic reports delay the reporting of suspicious orders … meaning that DEA cannot act quickly when necessary.'"[85] However, he concluded that the purpose of the language is "to impose a time period for 'informing' the Agency about a specific suspicious order."[86]

Consequently, when a manual or automated threshold system "discloses" the excessive/suspicious order that constitutes "when discovered" and triggers the reporting requirement. However, it is reasonable to permit a brief investigatory period to avoid the submission of reports that have been flagged by the system, but clearly are not suspicious as determined through verifiable and documented means. Therefore, based on the guidance provided by Acting Administrator Rosenberg's conclusions in the *Masters* case, it is my opinion that this investigatory period is less than a week. To permit a longer investigative period would only increase the likelihood that the DEA will be provided stale information if the order is ultimately reported as suspicious, which would run counter to the Agency's ability to properly investigate the order. It is also clear that the registrant must not ship the order until it is determined not to be suspicious and if the registrant cannot make a determination within the investigatory period, the order must be reported to the DEA and canceled.

5.4 Industry Guidance

In 1987, the National Wholesale Druggists' Association ("NWDA") developed, with input from the DEA, a suspicious order monitoring program.[87] The NWDA program or system provided, among other things, that "[s]ingle orders of unusual size or deviation must be reported [to the DEA] immediately ... [t]he submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting those single excessive or suspicious orders. DEA has interpreted 'orders' to mean **prior to shipment**."[88]

Building on the guidance provided by the DEA, Healthcare Distribution Management Association ("HDMA"), in 2008, developed voluntary industry guidelines to provide clear direction on how to develop a compliant anti-diversion program.[89] These general guidelines, which must be adapted by each individual distributor, cover the critical anti-diversion topics including:

- Know Your Customer Due Diligence;
- Monitoring for Suspicious Orders;

[85] *Id.*

[86] *Id.*

[87] *See NWDA "Suspicious Drug Order" Monitoring Program*, THE PINK SHEET (May 11, 1987), https://pink.pharmaintelligence.informa.com/PS011879/NWDA-SUSPICIOUS-DRUG-ORDER-MONITORING-PROGRAM. The National Wholes Druggists' Association became the Healthcare Distribution Management Association ("HDMA") in 2000 and in 2016 HDMA became the Healthcare Distribution Alliance ("HDA"). *See* HDA, *History,* https://www.hda.org/about/hda-history (last accessed Feb. 21, 2019).

[88] *See* Nat'l Wholesale Druggists' Ass'n, NWDA Suspicious Order Monitoring System, 7 (Jun. 21, 1993) (emphasis added), CAH_MDL2804_01465723.

[89] *See* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 13 (2008), WAGMDL00673706.

- Suspend/Stop an Order of Interest Shipment;
- Investigation of Orders of Interest;
- File Suspicious Order Reports with DEA;
- Employees, Training and Standard Operating Procedures; and
- Additional Recommendations.[90]

While the Compliance Guidelines incorporate the provisions found in the CSA, the DEA regulations, and the various guidance documents from DEA, they also add concepts not found in those documents. For example, it is in the HDMA guidelines that the term "orders of interest" appears. As defined by HDMA, "orders of interest" are "orders that warrant follow-up inquiry to determine whether they are suspicious."[91] Furthermore, it appears that the letter from Wendy Goggin, Chief Counsel for DEA, commending HDMA's efforts, is where the industry gets the mistaken belief that DEA "endorsed" the Compliance Guidelines, including the "orders of interest" concept.[92] Also, HDMA in the Industry Compliance Guidelines counseled, "[d]istributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report 'when discovered.'"[93]

[90] *Id.* at 3.

[91] *Id.* at 8.

[92] *See,* Letter from W. Goggin to J.M. Gray (Oct. 17, 2008) ("diversion control is not a 'one size fits all' effort), WAGMDL00673706.

[93] *See* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 13 (2008) (emphasis added), WAGMDL00673706.

PART III: Defining What Good Looks Like

6 Applying the Standards

As discussed in Part II, by the mid-1990s, the concept of "what good looks like" was established both in the context of corporate and controlled substances (a.k.a. anti-diversion) compliance. From that point forward it was clear that companies in the pharmaceutical industry, including manufacturers and distributors of opioid products, could develop effective internal controls to achieve the objectives to prevent and detect criminal conduct by an organization's employees and agents working on behalf of the organization and to guard against theft and diversion of controlled substances.[94]

In the U.S., the basic regulatory construct for pharmaceuticals, regardless of the agency, is to provide the industry with "what" is expected, but not dictate "how" those expectations are achieved. The "how" is left to the individual organizations to determine the best methods to comply. This approach is true in the case of the OIG, DEA, and even the FDA.[95]

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[94] *See* Appendix B, Figures 2 and 3 for diagrams outlining a controlled substances compliance program (a.k.a. anti-diversion program) and a corporate compliance program.

[95] *See, e.g.,* U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991) ["FSGs 1991"]; J. Rannazzisi letters to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007 and Jun. 12, 2012) (These letters were not McKesson specific but sent to all DEA registrants), MCKMDL00478906, MCKMDL00615308, MCKMDL00478910, MCKMDL00449807 ["DEA (date) Letter"]; U.S. Food and Drug Admin., Center for Drug Evaluation and Research, *Facts About the Current Good Manufacturing Practices (CGMPs),* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105 htm, (page last updated Jun. 25, 2018) (last accessed Dec. 8, 2018) ("The CGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures.").

6.1 General Principles

6.1.1 Corporate Compliance Programs

For any compliance program to be considered effective its basic building blocks must address the Seven, now Eight Elements of an Effective Compliance Program. These elements, whether for enterprise-wide or for controlled substances, are:

1. Organization and Resources
2. Due Diligence
3. Written Standards
4. Training & Communication
5. Monitoring, Auditing & Investigations
6. Corrective Actions
7. Enforcement (i.e., Discipline or other consequences for violating the standards)
8. Periodic Risk Assessment

While the eight elements provide a generally accepted and cohesive framework to assess compliance effectiveness, there is overlap between them, and therefore separating specific compliance activities by element is something of an esoteric exercise.

For purposes of simplicity and consistency when looking holistically across the entities assessed in my report, I grouped the eight elements listed above as follows:

Table 5.1-1 – Grouping the Eight Elements

Category	Elements of an Effective Compliance Program
Company Commitment	1. Organization and Resources (including company culture)
Program Core	3. Written Standards 4. Training & Communication 5. Monitoring, Auditing & Investigations 6. Corrective Actions 8. Periodic Risk Assessments
Accountability	2. Due Diligence (i.e., avoiding bad actors) 7. Enforcement (i.e., Discipline or other consequences for violating the standards)

Furthermore, although each type of compliance program has a specific focus (general enterprise-wide compliance versus controlled substances distribution compliance versus suspicious order monitoring), the

detailed standards applicable to all three types of compliance programs discussed here should be read together, as they reinforce and build-off each other.

Since the mid-1990's little has changed in the fundamentals in either the corporate compliance or controlled substances spheres, rather Main Justice, the DEA, and the OIG have become increasingly more pointed in reminding the pharmaceutical industry of what its statutory and regulatory obligations are with respect to corporate and controlled substances compliance. Even the introduction of new technology (e.g., ARCOS) has done little to change the fundamental compliance dynamic operating since 1995.

For example, in the context of monitoring compliance, technology arguably increases the amount of information that can be sorted, filtered and rapidly transmitted, but even today it merely provides an output of outliers and anomalies. Therefore, corporate and controlled substances compliance programs must still rely on experienced human resources, with intelligence and common sense, to review and understand the context surrounding each outlier or anomaly and then to apply the correct, balanced solution. Thus, in the end, good compliance comes down to experienced people making good choices.

It also comes down to the need for "objective evidence" to demonstrate that required compliance obligations including effectiveness, have been met. Thus, written documentation is the bedrock of demonstrating or "proving" that an organization's claims of effectiveness (or lack of thereof) are real. For example, as the Public Company Accounting Oversight Board ("PCAOB") points out in the context of audits:

> Inadequate audit documentation diminishes audit quality on many levels. First, if audit documentation does not exist for a particular procedure or conclusion related to a significant matter, its absence casts doubt as to whether the necessary work was done.[96]

The same applies to compliance efforts. Placing the PCAOB's comments about audit documentation into a compliance context:

> Inadequate **compliance** documentation diminishes **compliance** quality on many levels. First, if **compliance** documentation does not exist for a particular procedure or conclusion related to a significant matter, its absence casts doubt as to whether the necessary work was done.

This is the same point made by the House Energy and Commerce Committee report.[97]

Thus, if there is no documentation showing what is claimed was accomplished, the reasonable presumption is that it was not accomplished. Consequently, underlying all the applicable standards is the presumed need for good, written documentation to substantiate the existence and proper operation of compliance controls.

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[96] *See* PCAOB, *Audit Documentation and Amendment to Interim Auditing Standards*, PCAOB Release No. 2004-006 (Jun. 9, 2004) (Announcing adoption of Audit Standard No. 3 on audit documentation). Reference to the PCAOB is appropriate in this context because most of the distributors reviewed are publicly traded entities and thus must arrange for independent audits of their financial statements. For those entities that are privately-held, there remains a basic fiduciary duty to the owners and company directors that also necessitates good documentation exists.

[97] *See* WVA Red Flags Report at 124-125, 130 and 319 (repeatedly commenting on the lack of due diligence documentation by distributors).

6.1.2 Suspicious Order Monitoring Programs

Overall, a distributor's SOM program must meet a relatively short list of requirements:

1. There must be a system designed and operated to disclose suspicious orders of controlled substances.
2. The distributor must inform the local DEA Field Office when the distributor discovers a suspicious order.
3. At a minimum, orders are deemed suspicious if they are (a) of unusual size, (b) deviate substantially from a normal pattern, or (c) of unusual frequency.
4. Suspicious orders must be held and not shipped until it is determined that the order likely will not be diverted.[98]

As a threshold matter, the distributor or manufacturer must determine if the controlled substances customer is properly licensed to possess the controlled substance.[99] Both must also take steps to "know the customer," in other words, they need:

> to take reasonable measures to verify the identity of their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, detect those transactions that are suspicious in nature.[100]

As noted throughout this report, the "Know Your Customer" or KYC concept is critical to having a successful SOM program. To be effective, distributors and manufacturers must build and maintain profiles of their customers that are more specific than segregating those customers into various classes of trade. For example, knowing a pharmacy's product mix of controlled versus non-controlled prescriptions together with local data such as the number of residents, age as a percentage of residents, number and type of physicians and healthcare facilities, etc., are all important pieces of information that can make up a "Know Your Customer" profile. As the DEA makes clear, the Know Your Customer requirement is the basis for determining whether a customer's purchases are to be considered legitimate or diversionary. However, it also is important to remember that knowing one's customer and making determinations of whether orders are suspicious or legitimate is not simply a scientific endeavor (e.g., just using thresholds and algorithms), but also is an art requiring training, experience, innate skepticism, and common sense.

However, detecting and subsequently reporting suspicious orders are just a part of the overall set of controls a distributor and manufacturer needs to employ to prevent diversion. If "diversion" is taken to mean moving controlled substances into illegitimate "medical, scientific, [or] industrial channels"[101] or if it is taken to mean "the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use,"[102] then to

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[98] *See* 21 C.F.R. § 1301.74(b); *see also Masters Pharmaceuticals, Inc. v. DEA*, 15-1335 (D.C. Cir. 2017) (upholding DEA's interpretations of its regulations relative to defining a suspicious order and the timing of reporting).

[99] *See* 21 C.F.R. § 1301.74(a).

[100] *See* U.S. Dep't. of Justice, Drug Enforcement Administration *Chemical Handler's Manual*, 21 (2013) at https://www.deadiversion.usdoj.gov/pubs/manuals/chem/chem_manual.pdf.

[101] *See* 21 U.S.C. §§ 823 (b)(1).

[102] *See* Nat'l Conf. of Commissioners on Uniform State Laws, *Uniform Controlled Substances Act (1994),* § 309(a) (Dec. 28, 1995) at http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf.

prevent potential diversion, one needs to ensure that suspicious orders are not shipped until an appropriate investigation concludes that the risks of diversion occurring are not present.[103]

Taking it one step further, since maintaining effective controls against diversion is just part of a manufacturer and distributor's overall responsibility to exercise due diligence to prevent and detect criminal conduct, the controlled substances program and suspicious order monitoring system need to have controls, including but not limited to, conducting periodic risk assessments and undertaking appropriate corrective actions that flow from the company's compliance standards. Otherwise, that distributor or manufacturer cannot contend that it has maintained effective controls against diversion or that its corporate compliance efforts are effective.

6.2 Compliance Culture, Organization & Resources

The 2004 Federal Sentencing Guidelines ("FSGs") mandate that for an ethics and compliance program to be considered effective, it must promote "an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[104] As the OIG explained the year before in its 2003 Compliance Program Guidance, promoting and encouraging a commitment to ethics means:

> for a compliance program to be effective, it must have the **support and commitment of senior management** and the company's governing body. In turn, the corporate leadership should strive to **foster a culture** that promotes the prevention, detection, and resolution of instances of problems.[105]

For any compliance program to be successful, it must have adequate resources and the authority to achieve real compliance, and not just be delegated the responsibility for compliance.[106] In other words, responsibility without actual authority and appropriate resources is meaningless. Therefore, the culture of an organization, as well as the structure and resources are important elements of an effective compliance program.

Under the 2004 FSGs, in addition to requiring that high-level personnel in the organization be assigned responsibility for a compliance program, the Guidelines mandate:

- The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program [and]

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[103] *See* Letter from Wendy Goggin to John Gray (Oct. 17, 2008) (discussing HDMA's voluntary industry guidelines, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances.") WAGMDL00673706.

[104] *See* FSGs 2004 at § 8B.2.1(a)(2).

[105] *See* Dept. of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (emphasis added) ["OIG Pharma Guidance"]. The OIG has not issued specific compliance program guidance for distributors. However, the basic program elements discussed in the OIG Pharma Guidance are applicable to distributors as well.

[106] *See* FSGs 2004 at § 8B.2.1 (The "program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct.").

- Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.[107]

According to the OIG, while there are various ways to demonstrate a company's commitment to compliance, "[e]vidence of that commitment should include the allocation of adequate resources."[108] Therefore, "the compliance measures adopted ... should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience)," and "the compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully."[109] The 2017 compliance program effectiveness guidance documents from both the OIG and DOJ reiterate once more the importance of adequately resourcing the compliance function.[110]

6.2.1 Attributes

Within the context of a controlled substances compliance program, I would expect a good anti-diversion program for <u>both</u> a <u>manufacturer</u> and a <u>distributor</u> to have the following attributes:

1. **Integration:** The anti-diversion program is integrated into the overall fabric of the organization's corporate compliance program as directed by the Chief Compliance Officer ("CCO"). This can be evidenced by:
    a. Periodic reports from the Controlled Substances Compliance Team to the CCO, as well as mention of those efforts in the CCO's annual report to the Board of Directors.
    b. Participation in or periodic input to the Corporate Compliance Committee, either directly or through the appropriate functional leader (e.g., VP of Operations).
    c. Including an explicit controlled substances compliance expectation within the company's code of conduct.

2. **High-level individual:** The organization assigns responsibility and authority for the anti-diversion program to a relatively high-level individual or group including:

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[107] *See id.* at §§ 8B.2.1(a)(2)(A) and(a)(2)(C).

[108] *See* OIG Pharma Guidance at 23732.

[109] *Id.* at 23732 and 23739.

[110] *See* HCCA-OIG Compliance Effectiveness Roundtable, Measuring *Compliance Program Effectiveness: A Resource Guide*, at 12 (Mar. 27, 2017), available at https://oig.hhs. gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf ["HCCA Effectiveness Guidance"]; U.S. Dep't of Just., Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (Feb. 8, 2017), 2-3 <u>https://www.justice.gov/criminal-fraud/page/file/937501/download</u> ["DOJ Compliance Evaluation"].

a. Designating a Vice President level, but no lower than Senior Director, as the highest-ranking person in charge of the anti-diversion program.
b. If the program is assigned to someone with additional duties and responsibilities, using the company HR performance review process to assure that he or she understands the success of the anti-diversion program is a key component to their overall compensation package.
c. If the program is embedded in an operations group (as opposed to the Office of the Chief Compliance Officer), the creation of an independent reporting line to the CCO.
d. Compliance determinations by the high-level individual or group, including customer acceptance/termination and processing of "flagged" orders are appealable only to the CCO or the Compliance Committee, and their decision is final.
e. The organization maintains current, accurate organizational charts applicable to the anti-diversion program.

3. **Resources:** The organization provides adequate budget and headcount to carry out the activities of the anti-diversion program effectively.
    a. The budget allows for enough travel funds to conduct onsite visits and investigations and provides some funding to hire outside support as needed.
    b. If the company leverages indirect reports (e.g., using internal audit staff to conduct customer investigations), using the company HR performance review process to assure that the indirect reports understand that supporting the anti-diversion program is a key component to their overall compensation package.

6.3 Written Standards & Education

Having established written policies and procedures (standards) is fundamental to having an effective compliance program.[111] Written standards serve as the basis for instructing an organization's employees not only what tasks need doing (policy) but how they need to accomplish those tasks (procedure). Written standards also are important to ensure consistent outcomes are achieved from the processes the organization utilizes.

While the exact format of policies and procedures vary by organization, there are standard elements common to all policies and procedures, especially in the pharmaceutical industry.[112] From a compliance program effectiveness standpoint, scope (do the standards encompass what needs to be addressed?), clarity (are the standards understandable?), accountability (do employees know what they are accountable for and when they must involve the gatekeepers?), and accessibility (can employees find the officially approved standards to read them?) are primary factors in determining whether policies and procedures will be effective.[113]

[111] *See* FSGs 2004 at § 8B.2.1(b)(1).

[112] *See, e.g.,* Margret Amatayakul, *Practical Advice for Effective Policies, Procedures*, 74 J. OF *AHIMA*.4: 16A-D (Apr. 2003), http://library.ahima.org/doc?oid=59451#.XBfhIfZFwuW. For a list of those standard elements, see Appendix B, Figure 1.

[113] *See* HCCA Effectiveness Guidance, at 3-4; DOJ Compliance Evaluation, at 3-4; *see also* ISO 9001:2015 (outlining the basic concepts of good document control).

The centerpiece of an organization's collection of written standards, which include company policies and operational procedures, is a core statement of ethical and compliance principles commonly referred to as the "Code of Conduct." The Code of Conduct is the statement of the organization's fundamental principles and values, as well as the expectation that employees will be committed to compliance.[114] A Code of Conduct, while not expressly required by the Federal Sentencing Guidelines, nevertheless has been a leading practice since the late 1990's, and is an important mechanism for a company "to communicate effectively its standards and procedures to all employees and other agents" because Codes of Conduct are "publications that explain in a practical manner what is required."[115] The OIG also has enshrined the need for a Code in its OIG Program Guidance.[116]

While established written policies and procedures are critical, just having them is not enough for a compliance program to be effective. An organization's employees must know that those standards exist (communication) and what is expected from each employee (training or education).[117] Communicating those standards and expectations is not a "once and done" proposition.[118] Because the compliance environment is dynamic with many moving parts (e.g., new hires, new regulations, new policies, new organizational structures, etc.), as well as the fact that people generally need to hear the information more than once to absorb it (e.g., the marketing rule of seven), good compliance functions generally expend significant resources on communication and training.

Furthermore, it is an industry leading practice to require employees to demonstrate mastery of the information being imparted in training (e.g., education) via a test or assessment. Passage of such an assessment provides some modicum of objective evidence that the trainee was effectively trained. The most rigorous programs, especially those using eLearning systems, require the trainee to successfully answer two or three questions after each section to progress and then to pass a final assessment at the end. For "live" or "real-time" training sessions, leading practice is to employ a "sign-in sheet" or some other mechanism to capture attendance. In both cases, the data on attendance and successful completion are normally maintained in an employee's training record, sometimes referred to as their "training jacket," which can be either a digital record or paper file.

6.3.1 Attributes

Within the context of a controlled substances compliance program, I would expect the written standards in a good anti-diversion program for <u>both</u> a <u>manufacturer</u> and a <u>distributor</u> to have the following attributes:

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[114] *See, e.g.,* OIG Pharma Guidance at 23733.

[115] *See* FSGs 2004 at § 8B.2.1(b)(4).

[116] *See, e.g.,* OIG Pharma Guidance at 23733.

[117] *See* FSGs 2004 at § 8B.2.1(b)(4). ("The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subdivision (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.").

[118] *Id.*

1. **Standard Elements:** The written standards incorporate the standard elements common to all policies and procedures in the written standards, including but not limited to Title, Purpose, Scope, Responsibilities, Effective Date, and Revision History.[119]
    a. Key terms (e.g., thresholds) are defined either directly in the written standards or via a separate glossary of terms.
    b. Employees can clearly determine what they will be held accountable for and when they must involve the gatekeepers.
    c. Where discretion is granted to gatekeepers, the standards define the criteria used in making those decisions.

2. **Document Control:** The written standards are developed, revised and approved utilizing a formal document control process.
    a. The process, at a minimum, tracks approvals, revisions and the reason for any changes.
    b. The process ensures that obsolete versions of the standards are withdrawn from use, but maintains withdrawn copies in an archive.
    c. Depending on the size of the organization, the document control process may be either paper-based or electronic.
    d. All archived versions of written standards are stored and maintained as essential compliance and business records.

3. **Publication:** The written standards are maintained in a form and location readily accessible to all employees.
    a. Depending on the size of the organization, publication may be either paper-based (e.g., a manual) or via electronic media such as a company intranet.

Education in a good anti-diversion program would have the following attributes:

1. **Acknowledgment of Standards:** Employees with controlled substances responsibilities acknowledge receipt and having "read and understood" the issued standards in a timely manner (e.g., 10 days).
    a. Those acknowledgments are collected, tracked, and follow-up occurs for missing or incomplete acknowledgments.

2. **Good Training Practices:** All employee education courses follow good training practices including:
    a. Depending on the size of the organization, the courses are delivered by face-to-face or eLearning methods.
    b. Courses follow the principles of good instructional design (e.g., limited duration, information not densely packaged, etc.).[120]
    c. Session attendance and overall completion are tracked, and follow-up occurs for missing records or incomplete training.

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[119] For a complete list of standard elements, see Appendix B, Figure 1.

[120] *See, e.g.*, Presentation Mike Kunkle, *Instructional Design Primer*, (Feb. 6, 2011), https://www.slideshare.net/MikeKunkle/basic-instructional-design-principles-a-primer (last accessed Mar. 14. 2019). This is presentation is illustrative of the fact that information on good instructional design is widely and readily available.

d. Successful completion of the course by employees is based on an objective assessment or test demonstrating comprehension of the topics covered.
e. Failure to successfully complete a course after 2 or 3 attempts triggers additional follow-up and counseling by the employee's manager and compliance as assisted by HR.
f. Every employee has an accurate record of any educational courses completed during their career with the company that is maintained in a readily retrievable format (e.g., a "training jacket" or Learning Management System ("LMS") file).
g. The education record, at a minimum, contains course, title, and date, instructor name or LMS file name, and completion outcome (e.g., pass or fail).
h. All educational course materials and individual educational records are stored and maintained as essential compliance and business records.

3. **Controlled Substances Education:** Employees with responsibilities for controlled substances compliance complete required education courses.
   a. Education courses for newly hired employees are completed before the new employees can work alone.
   b. Refresher education courses are conducted on an annual basis.

4. **General Compliance Education:** All employees receive a level of periodic compliance education that includes how to raise questions, as well as reporting issues of suspected misconduct.

5. **Other Educational Methods:** The organization uses other means and methods (e.g., periodic newsletters, "email blasts," etc.) to routinely engage with employees and keep them abreast of impending changes to the anti-diversion program or to solicit employee feedback.

6.4 Monitoring, Auditing & Investigations

Detection or due diligence is at the heart of an effective compliance program.[121] This concept of detection involves three different but interrelated activities (monitoring, auditing, and investigations). Although sometimes used interchangeably, monitoring, auditing and investigations differ in scope and application, but do all ultimately involve looking for anomalous behavior or outliers that need correcting.[122]

Effective Suspicious Order Monitoring Programs also utilize all three concepts. However, unlike a general corporate compliance program, a SOM program does not simply involve monitoring, auditing and investigating

[121] *See* FSGs 2004 at § 8B.2.1(a)(1).

[122] Monitoring is a continuous, real or near-real time activity using established criteria to demonstrate adherence to specific standards. Audits are retrospective, "snapshots in time" to provide assurance that employees are adhering to the required process. Transactional testing is used in audits to verify that the process truly is being followed. Investigations involve examining specific circumstances or individuals to determine if breaches of company policies, procedures or the law have occurred.

internally to ensure the employees are following the prescribed standards, but also applies these activities externally to its customer base as part of the system of controls for preventing diversion.[123]

By reviewing the DEA regulations and general guidance letters provided to all registrants during the review period, it is possible to get a clear concept of what a successful SOM program should look like. Below is a summarized list of SOM requirements derived from those sources:

1. The customer must be "known" to determine that the customer can lawfully receive the shipment.[124]
2. There must be a designed system.[125]
3. It must be operational. [126]
4. It must identify suspicious orders of controlled substances. [127]
5. Orders can be suspicious because of: [128]
   a. unusual size;
   b. substantial deviation from a normal pattern; or
   c. unusual frequency.
6. Once a suspicious order is discovered,
   a. the local DEA Field Office must be informed,[129] and
   b. the order must be prevented from being filled until it can be ascertained that the order will not be diverted.[130]

Utilized correctly, the establishment of thresholds (a cap on the amount of controlled substances a customer can order in a set period) is an effective way to identify, but not confirm, suspicious orders. Once identified as suspicious, the reasonable, and required steps, include placing a "hold" or "stop notice" on the order to prevent the product from potentially being diverted, immediately notifying the appropriate DEA field office or DEA headquarters or immediately conducting an appropriate investigation to determine if the suspicious order is indeed a potential diversion situation.

Only after the investigation determines that the risk of diversion is not present, can the shipment be processed in the usual course. However, if the investigation determines that there is a risk of diversion, the order must not be filled, and the company should contemplate other appropriate steps for handling future shipment requests. Those steps include refusing to ship any more products to the customer, requiring the customer to provide independent assurance that a diversion situation is not present, or terminating the customer altogether.

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[123] *See* 21 C.F.R. §§ 1301.74 (a-b); DOJ Compliance Evaluation at 7 (third party management); James Arnold 6/2013 Presentation at 42-53; Presentation by G. Boggs, *State of Prescription Drug Abuse*, 39 (2013), MCKMDL00336833; *see also* McKesson, *McKesson Operations Manual for Pharma Distribution, Controlled Substances Monitoring Program*, 56 (Aug. 24, 2011), MCKMDL00000021 ("McKesson's responsibility is to "Know our Customer.").

[124] *See* 21 C.F.R. § 1301.74(a).

[125] *See* 21 C.F.R. § 1301.74(b).

[126] *See* 21 C.F.R. § 1301.74(b).

[127] *See* 21 C.F.R. § 1301.74(b).

[128] *See* 21 C.F.R. § 1301.74(b).

[129] *See* 21 C.F.R. § 1301.74(b).

[130] *See* DEA 6/12/2012 Letter at 2.

6.4.1 Attributes

A. Distributors

Within the context of a controlled substances compliance program, I would expect the monitoring, auditing, and investigations program for a robust distributor anti-diversion program to have the following attributes:

1. **Know Your Customer:** The distributor has and maintains current granular and specific knowledge about each retail pharmacy customer and their unique circumstances.
    a. Customer background information:
        i. Is collected on all customers, including national retail chains, before any product sales are made.
        ii. Is collected using a standard methodology (e.g., a questionnaire) that balances the need to see patterns and trends amongst similarly situated customers, with the flexibility to capture unique circumstances.
        iii. Includes more than DEA and state Board of Pharmacy licenses to include available internet or commercially obtainable information (e.g., GOOGLE searches, Dun & Bradstreet reports, IMS data, etc.).
        iv. Includes dispensing data and largest prescribers.
        v. Includes whether the relationship is primary (e.g., exclusive) or secondary.
        vi. Includes the customer's prior overall compliance history that is not limited to just controlled substances.
        vii. Uses a risk-adjusted process for periodically re-evaluating customers considering changed circumstances. Those risk factors include the indicators of diversion provided by the DEA as well as changes in control (e.g., merger, acquisition, the sale of a business) or customer profile (e.g., new pain clinic in the territory served).
        viii. Obtains references from the primary distributor when known.
        ix. Is kept current and updated on a regular, periodic basis.
    b. Customer background information is evaluated for completeness and accuracy.
        i. Submissions of inaccurate or incomplete information are grounds for immediate disqualification or termination.
        ii. Refusal to provide requested background information is grounds for immediate disqualification or termination.
        iii. In the case of the large retail pharmacy chains (e.g., CVS, Walgreens, and Rite Aid) defines "customer" in terms of the individual retail pharmacy location and not just the national chain.
    c. Customers are evaluated and approved or denied based upon submitted background information and any other due diligence conducted by the organization.
        i. Evaluations occur under established criteria, which, at a minimum, incorporate any guidance from the DEA.
        ii. "Red flags" such as being a secondary supplier or customer being recently terminated by another distributor trigger a thorough investigation including a site visit by a trained investigator.
        iii. Outcomes are clear and well-documented.

   d. Customer site visits are routinely and periodically performed even after an initial site visit.
      i. Site visits are performed by individuals trained in diversionary behaviors.
      ii. If sales personnel are utilized to perform site visits, steps are taken to minimize conflicts of interests (e.g., using out-of-territory personnel).
   e. Customer files are stored and maintained as essential compliance and business records.

2. **Thresholds:** The organization uses threshold calculations based on dosage units to identify "suspicious orders."
   a. Thresholds are customer-specific and set using the background information obtained and maintained by the organization in accordance with the organization's written standards.
   b. Like customers are grouped together with as much granularity as possible (e.g., business activity, purchasing patterns, total prescriptions, geographic location, size of territory served).
   c. Thresholds are calculated based on multiple criteria using a documented, validated statistical formula that considers, at a minimum, the following items:
      i. Customer group;
      ii. Order size, patterns, and frequency, both individually and of the group; including orders being filled by other distributors;
      iii. Dispensing data, both individually and of the group;[131]
      iv. Geographic territory and population served;
      v. Product formulation (active ingredient and dosage) as well as the diversion potential; and
      vi. Legitimate, medically necessary, dosage unit levels developed based upon the approved indications for use and without regard to current opioid purchasing patterns.
   d. A minimum of 12-months of relevant and complete historical data is used without "cherry picking" the most favorable data.
   e. Actual thresholds and the threshold calculation methodology are not shared with customers.
   f. Thresholds are binding until an approved threshold exception or adjustment is granted.

3. **Threshold Exceptions or Adjustments:** Any threshold exceptions or adjustments rarely are made when viewed by the individual customer or the group, as well as a simple review of request frequency.
   a. Threshold exceptions or adjustments are made by a committee of individuals with anti-diversion experience and training in accordance with the organization's written standards.
   b. All threshold exceptions or adjustments are supported by verifiable objective evidence that is documented in writing.
   c. Threshold exceptions and adjustments are tracked and trended on both a short-term (e.g., weekly or monthly) <u>and</u> long-term (e.g., quarterly or annual) basis.
   d. All threshold exceptions or adjustments, including any records of approvals or denials, are stored and maintained as essential compliance and business records.

4. **Taking Action:**

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[131] With the appropriate safeguards to protect patient identifiable health information under HIPPA and other relevant privacy standards.

a. All orders which exceed the customer-specific threshold are deemed "suspicious" and reported to the DEA within one week unless it is determined that there are no reasons to suspect that a customer is engaging in diversion; for example, a clerical mistake (e.g., "fat-finger" orders).
b. All orders exceeding thresholds are held and not shipped. No order "cutting" is permitted.
c. No orders exceeding thresholds may ship until a thorough independent investigation is completed based on verifiable objective evidence demonstrates that diversion is unlikely to occur, and the findings are reviewed and approved.
    i. The use of the Corporate Headquarter staff of the large retail pharmacy chains (e.g., CVS, Walgreens, and Rite Aid) as the "lead investigator" is not permitted to maintain independence.
d. No future orders involving the same active ingredient are processed or shipped until the thorough independent investigation is completed based on verifiable objective evidence that demonstrates diversion is unlikely to occur and the findings are reviewed and approved.

5. **Audits:** The distributor's internal audit team, or an appropriately qualified third-party (e.g., the company's external auditors) conducts periodic, regular audits of the distributor's anti-diversion program including transactional testing of a statistically relevant sample of retail pharmacy customers.
    a. All customer supply contracts contain the appropriate "right-to-audit" clause.
    b. All audits are conducted in accordance with written standards.
    c. Audits are conducted on a risk-adjusted basis.
    d. Audit findings and corresponding management responses are tracked and trended.
    e. Repeat audit findings are escalated to the organization's Chief Executive Officer and the Audit Committee of the Board of Directors.

B. Manufacturers

For a <u>manufacturer's</u> anti-diversion program, I would expect to see:

1. **Know Your Customer:** The manufacturer has and maintains current granular and specific knowledge about <u>each distributor</u> of its controlled substances and their unique circumstances including all the information outlined in the distributor section above.
    a. Distributor site visits are undertaken to review the distributor's anti-diversion controls both at initiation of the relationship and then periodically on a risk adjusted basis thereafter (see Audits section below).
    b. Utilize, where appropriate, information derived from chargeback data.

2. **Individual Retail Pharmacy Activity:** Like the distributor thresholds outlined above, the manufacturer establishes ordering levels for specific pharmacies, which if exceeded trigger the manufacturer to be concerned that the orders are "suspicious," and that action is needed.
    a. Where appropriate, information obtained through the manufacturer's sample accountability (e.g., PDMA) program is factored into the controlled substances monitoring program.
    b. Wherever possible, the manufacturer leverages synergies (people, process and technology) between the sample accountability and controlled substances compliance programs.

3. **Taking Action:** When the manufacturer gains knowledge of retail pharmacies placing "suspicious orders" or otherwise engaging in diversionary behavior (e.g., serving questionable prescribers), the manufacturer takes the following actions:
   a. The manufacturer notifies and provides details of the suspicious activity to both the DEA and the distributor.
   b. The manufacturer demands the distributor, and any secondary distributor if known, follow-up and take appropriate action regarding the highlighted pharmacies.
   c. The manufacturer maintains contact with the distributor, and any secondary distributor if known, requiring them to provide details on the outcome of any investigations including actions taken by the distributor(s) against the pharmacies.

4. **Audits:** The manufacturer conducts both routine and "for cause" audits of those distributors' anti-diversion programs.
   a. All customer supply contracts contain the appropriate "right-to-audit" clause.
   b. Routine audits are conducted on a risk-adjusted basis.
   c. All audits are conducted in accordance with written standards.
   d. Audit findings and corresponding management responses are tracked and trended.
   e. Repeat audit findings are escalated to the organization's Chief Executive Officer and the Audit Committee of the Board of Directors.

6.5 Corrective Actions & Risk Assessments

Once non-compliant conduct, whether criminal or not, has been detected by monitoring and confirmed to have occurred through investigation, the organization is expected to determine and implement changes to avoid either a continuation of the underlying conduct, or to prevent a new occurrence from arising.[132] As the OIG elaborated:

> Violation of a pharmaceutical manufacturer's compliance program, failure to comply with applicable federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry. **Detected but uncorrected misconduct can endanger the reputation and legal status of the company**.
>
> Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and if so, take **decisive steps** to correct the problem.[133]

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[132] *See* FSGs 2004 at § 8B.2.1(b)(7) ("After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.").

[133] *See* OIG Pharma Guidance at 23742 (emphasis added); HCCA Effectiveness Guidance at 50-51 §§ 7.43-7.54.

The DEA regulations also embody the corrective action concept.[134] Identified corrective actions need to be documented and monitored to ensure they are implemented. This is especially true for complex corrective actions that often span many weeks or months to accomplish.

For a compliance program to be effective, just correcting errors, omissions and breaches are not enough. Organizations also need a documented process to conduct risk assessments.[135] The risk assessment process captures changes as various risks morph (e.g., the emergence of internet pharmacies dispensing controlled substances), as well as what the organization is doing to address or mitigate those risks and to assess whether those activities are working.[136]

Typically, when companies first embark on establishing a compliance program, they engage in a risk assessment, more often referred to as a "gap analysis." This gap analysis provides the compliance program designers with crucial information on what needs to be addressed.

However, risk assessments normally are not a single event. The risk assessment process envisioned by the FSGs is a true, repeatable process that should occur at regularly scheduled intervals. Therefore, while the gap analysis is usually done at the beginning, the formal risk assessment process frequently is established after the basic compliance program framework is in place.

6.5.1 Attributes

Within the context of a controlled substances compliance program, I would expect the corrective action and risk assessment processes for <u>both</u> a robust <u>distributor</u> and <u>manufacturer</u> anti-diversion program to have the following attributes.

1. **Corrective Actions:** The organization has a formal, documented corrective action process, and applies that process to the anti-diversion program:
    a. All program deficiencies are documented regardless of source (e.g., internal or external audits, internal or external assessments, regulatory inspections, regulatory guidance, and industry standards).
    b. For every documented deficiency, a plan for correction, which details the remedy, employees' responsible for making the corrections and plan milestones, is developed.
    c. The final approved plans are collected and tracked with corresponding updates to the Compliance Committee, Senior Management and if warranted the Audit Committee of the Board of Directors.
        i Whenever possible, corrective action documentation and tracking are incorporated into the organization's electronic Governance, Risk and Compliance or e GRC system (e.g., Archer).

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[134] *See, e.g.,* 21 C.F.R. § 1301.71(c).

[135] *See* FSGs 2004 at § 8B.2.1(c) ("In implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.").

[136] *See* DOJ Compliance Evaluation at 4-5, Topic 5; HCCA Effectiveness Guidance, at 15 §§ 2.56-2.62.

d. Plan timelines have a finite time limit (e.g., no more than 12 months)
   i If additional time is necessary to complete the corrective action, a new plan is submitted and approved.
   ii Senior Management and Compliance approval is required for any extensions.
e. Individual accountability is managed through the standard HR performance appraisal process.
f. Corrective action items are only closed upon independent verification that the planned corrections are complete and functioning as intended.

2. **Risk Assessments:** The organization maintains a formal, documented risk assessment process to evaluate legal and compliance risks to the organization's anti-diversion program. A robust process includes, but is not limited to, the following elements:
   a. The process evaluates both internal and external risks to the anti-diversion program.
   b. The process leverages data from all available sources, including but not limited to:
      i Budgets;
      ii Headcount;
      iii Exit interviews;
      iv Employee surveys;
      v Investigation results;
      vi Audit results;
      vii Corrective actions;
      viii Commercial benchmarking data (e.g., IMS data);
      ix Regulatory inspections; and
      x Enforcement actions.
   c. A risk assessment review occurs at defined intervals, but no less than annually.
   d. The risk assessment output is documented and is:
      i Disseminated widely to management, compliance, legal, internal audit and those responsible for the anti-diversion program.
      ii Maintained in a readily digestible format such as a "heat map."
      iii Incorporated, whenever possible into the organization's eGRC system.
      iv Used to develop further corrective actions, audit planning, budget and headcount increases, customer monitoring efforts, etc.
   e. Previous risk assessment outputs are maintained and utilized for benchmarking and trending purposes to show improvement or decline in the effectiveness of the anti-diversion program.

6.6 Accountability - Consistent Enforcement

Accountability also is a fundamental element of an effective compliance program. Under the FSGs, there are two intertwined provisions that apply in this context. The first involves consistent enforcement of compliance

and ethical standards, including government requirements, otherwise known as discipline.[137] The second involves being careful with the delegation of substantial authority, otherwise known as "avoiding bad actors."[138]

6.6.1 Discipline

In the case of consistent enforcement, the FSGs succinctly notes "[a]dequate discipline of individuals responsible for an offense is a necessary component of enforcement."[139] The OIG Compliance Program Guidance goes further stating:

> Intentional and material noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. **Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct**.[140]

6.6.2 Avoiding "Bad Actors" – Employees or Customers

The FSGs also requires organizations to "use reasonable efforts" to ensure that "with the substantial authority personnel of the organization any individual whom the organization knew or should have known through the exercise of due diligence, has engaged in illegal activities or **other conduct inconsistent with an effective compliance and ethics program**" are not placed in a position to cause harm through their non-compliant actions.[141]

The FSGs defines "substantial authority personnel" as:

> individuals who within the scope of their authority exercise a substantial measure of discretion in acting on behalf of an organization. The term includes high-level personnel of the organization, individuals who exercise substantial supervisory authority (e.g., **a plant manager, a sales manager**), and any other individuals who, although not a part of an organization's management, nevertheless exercise substantial discretion when acting within the scope of their authority (e.g., an individual with **authority** in an organization **to negotiate or set price levels** or an individual authorized to negotiate or approve significant contracts).[142]

While the FSGs focuses primarily on organizational and employee accountability, the CSA and its implementing regulations focus on customer behaviors. Embedded within the concept of identifying suspicious orders and having effective diversion controls is the common sense proposition that if an order is initially

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[137] *See* FSGs 2004 at § 8B2.1(b)(6).

[138] *See* FSGs 2004 at § 8B2.1(b)(3).

[139] *See* FSGs 2004 at § 8B2.1, Application Note 5.

[140] *See* OIG Pharma Guidance at 23742 (emphasis added).

[141] *See* FSGs 2004 at § 8B2.1(b)(3) (emphasis added).

[142] *See* FSGs 2004 at § 8A1.2, Application Note 3(c) (emphasis added).

flagged as suspicious using the criteria in the DEA regulations (unusual size, pattern, frequency), the distributor must not ship that order or any similar controlled substances order to that customer until the distributor determines whether or not there is likelihood the shipment is being diverted.[143] To do otherwise, potentially allows a diversionary situation to continue, which is the opposite of preventing diversion.[144] In other words, the distributor is expected to impose discipline on its customers when the distributor becomes aware of customers that are placing suspicious orders.

6.6.3 Attributes

1. **Employees:** The organization (both <u>distributors</u> and <u>manufacturers</u>) maintains a robust screening (background check) process and a disciplinary system that includes appropriate sanctions up to and including termination.
    a. Employees alleged to have violated any anti-diversion requirements are immediately removed from any further responsibilities involving controlled substances until cleared by a thorough independent investigation demonstrating that no violation occurred based on verifiable objective evidence.
    b. Employees who violate the requirements of the organization's anti-diversion program are subject to appropriate disciplinary sanctions.
    c. Disciplinary sanctions are routinely and consistently enforced regardless of an employee's level in the organization or previous job performance.

2. **Distributor Customers:** Retail pharmacy customers, failing to comply with any requirements of the distributor's anti-diversion program (e.g., providing incomplete or inaccurate information) are subject to immediate disqualification or termination.
    a. This requirement is explicitly stated in all customer supply contracts.
        i. Contracts contain a "for cause" immediate termination provision, which includes being non-compliant.
    b. Disqualifications and terminations are routinely and consistently enforced regardless of a customer's prior purchasing history.
    c. Any pending shipments are immediately canceled.
    d. Disqualified or terminated customers are not eligible for reinstatement until a thorough audit is conducted and any corrective actions by the customer are verified via objective evidence demonstrating that the customer has effectively corrected <u>all</u> issues underpinning the disqualification or termination.

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[143] DEA 2/7/2007, 12/27/2007, 6/12/2012 Letters at 2; *see also Southwood Pharmaceuticals, Inc*., Revocation of Registration, 72 Fed. Reg. 36487, 36500 (Jul. 3, 2007) (Holding the distributor accountable for not stopping shipments to customers it should have known were placing suspicious orders including those customers DEA told the distributor were engaging in suspicious ordering).

[144] *See* 72 Fed. Reg. at 36500 ("In short, the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone. Indeed, it is especially appalling that notwithstanding the information the Respondent received from both this agency [DEA] and the pharmacies, it did not immediately stop distributing hydrocodone to any of the pharmacies. Moreover, in several cases, Respondent actually distributed even larger quantities of the drug to them.")

i. Reinstatement of disqualified or terminated customers is reviewed and approved by either the CCO or Compliance Committee.

e. Notices of customer disqualifications or terminations are communicated as soon as possible to the distributor's sales representatives.

i. The distributor adjusts sales representative compensation plans to remove any negative impact from disqualification or termination.

3. **Manufacturer Customers**: Distributor customers of the manufacturer, which distribute the manufacturer's prescription opioid products are subject to appropriate disciplinary sanctions up to and including termination of the relationship.
   a. This requirement is explicitly stated in all customer supply contracts.
      i. Contracts contain a "for cause" immediate termination provision, which includes being non-compliant either with the manufacturer's anti-diversion requirements or when cited by the DEA.
   b. Contracts allow for the immediate cessation of chargebacks for prescription opioid products to non-compliant retail pharmacy customers.

6.7 Manufacturer – Prescriber Relationship

Opioid manufacturers within the DEA's "closed-loop" system, unlike distributors, also are uniquely positioned to observe prescriber behaviors. This occurs because the manufacturers' field forces make routine sales calls on prescribers' offices. Thus, the field forces can be exposed to some of "red flag" indicators such as overly full waiting rooms, young patients, people nodding off in the waiting room, etc.[145] Put another way, things that "if you were to walk into a doctor's office would give you pause and would make you turn around and walk out."[146] The same is true for information obtained from other sources such as IMS data, or media reports.

Given this unique vantage point, the prudent and responsible manufacturer should instruct and require its sales representatives, and in-house field support and marketing personnel, to provide any observations of potential diversionary behavior to their in-house Compliance Department for further evaluation and potential action. As Acting Administrator Rosenberg noted in the Masters Pharmaceutical proceedings, "a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices" or more specifically, "a registrant cannot claim that it … has an effective suspicious orders monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices."[147] While the company needs to act with care to be objective (which is true for every compliance investigation), "turning a blind eye" is not an option.

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[145] *See* Scott Glover and Lisa Giron, OxyContin maker closely guards its list of suspect doctors, LOS ANGELES TIMES (Aug. 11, 2013), https://www.latimes.com/local/la-xpm-2013-aug-11-la-me-rx-purdue-20130811-story.html.

[146] *See id.* (quoting Robin Abrams, attorney for Purdue Pharma and a former federal prosecutor specializing in federal healthcare fraud).

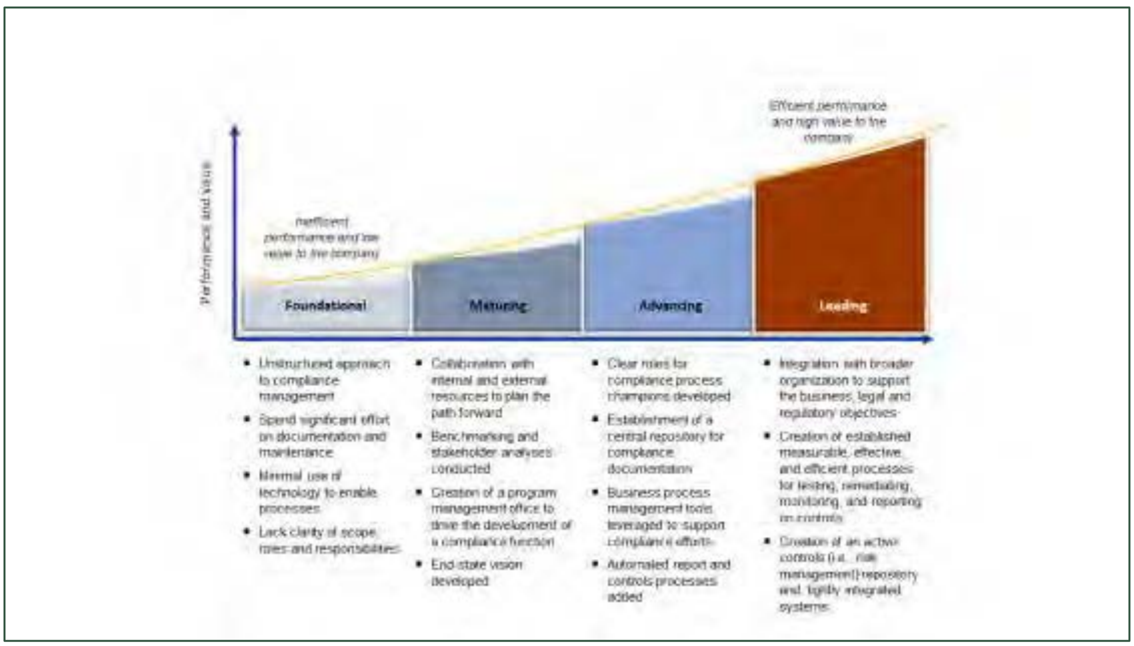
[147] *See* 80 Fed. Reg. 55418, 55478 (Sept. 15, 2015).

Upon receipt of this information, the Compliance Department, or other experienced investigators, should conduct an appropriate investigation to determine the validity of the information, using all available sources of information (e.g., the internet, IMS data, etc.), and if confirmed, formulate an appropriate action plan. Depending on the weight of the evidence gathered, that plan can range from conducting further comprehensive monitoring activities to refusing to make further sales calls on the suspect practices to, in the most egregious cases, providing the information to the appropriate authorities, including the DEA and State Medical Boards.

7 Measuring What Good Looks Like

After defining "what good looks like" the next step is to measure it. Measuring compliance effectiveness or "what good looks like" is not simply a matter of taking the attributes and applying a statistical, or even a generally recognized standard scoring methodology, as one does not exist. The best approximation of a standardized scoring model is the compliance maturity and program effectiveness model, which outlines the typical evolutionary pathway most compliance organizations follow.

Figure 2– Compliance Maturity & Program Effectiveness Model



The model sets out a framework outlining what characteristics distinguish a compliance function that is just starting out or where management does not embrace the value of the program from one which is fully embedded into company operations and where management clearly recognizes the value that strong compliance provides. Since the levels of maturity directly correlate to the effectiveness of the compliance program, this model also provides a way to level-set among companies in the same field (e.g., pharmaceutical distribution). Overall, most companies focus on and strive to be in either the advancing or leading categories.

This report first analyzes each distributor's and a single manufacturer's overall compliance efforts surrounding controlled substances by starting with suspicious order monitoring. For each company, the analysis focuses on answering two questions. The first question is whether objective evidence exists supporting that the company

being reviewed worked to establish a suspicious order monitoring system, as well as controlled substances and corporate compliance programs. Only if there is evidence that the company did so is the second question relevant.

The second question is whether there is objective evidence showing that the company met its three-prong program effectiveness requirement by (a) having a program that prevents and detects criminal conduct by an organization's employees and (b) maintaining effective controls against diversion, including (c) maintaining and operating an effective system to identify, hold, investigate and report suspicious orders of controlled substances.

PART IV: Report Overview

8 Executive Summary

8.1 Group 1 Distributors

The Group 1 ("G1") distributors (also known as the "Big Three"), on a national basis, account for 85% of the national drug supply.[148] Although each G1 distributor's detailed approach to both corporate compliance and anti-diversion controls for controlled substances was reviewed separately, there are common threads that unite all three companies.

[148] *See* W.Va. Red Flags Report at 7.

First, even though the applicable standards for controlled substances and corporate compliance were established in the early 1970s and 1990s respectively, all three distributors did not establish their own programs until years later. Nor did they make their controlled substances efforts part of their overall corporate compliance programs in a meaningful way.

Second, prior to having significant pressure brought to bear on them by the DEA for non-compliance, none of the three companies made more than token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market, let alone to fulfill the required legal and regulatory obligations. In so doing, all three failed to manifest good corporate responsibility by not undertaking the reasoned, prudent and careful measures expected of those handling prescription opioid products.

Third, despite entering into settlement agreements to operate effective anti-diversion and SOM programs and claiming to be working with the DEA, each distributor designed, implemented and operated their controlled substances program in such a manner as to avoid classifying customer orders as "suspicious" in order to avoid having to stop suspect opioid shipments to customers. Even after the DEA directed them to act, every G1 distributor failed to make the necessary changes in order to achieve a robust and effective compliance function in accordance with the values, principles and societal expectations for those involved in distributing prescription opioids.

Fourth, when confronted with objective evidence of inappropriate opioid ordering, each company still did not make reasonable inquiries as to "why" it was occurring. By doing so, all three companies studiously avoided having to address customer behaviors they knew or should have known were inappropriate and likely diversionary.

In short, throughout the review period, the big three distributors failed to act responsibly to undertake the reasoned, prudent and careful measures expected of those handling prescription opioid products even while acknowledging the exponential increase in opioid usage. Customer relationships simply trumped compliance. As a result, on the compliance maturity and program effectiveness model, all three score no higher than the midpoint of the foundational level, which is unacceptable and unreasonable given how long these standards have existed, the resources available to each company and the evidence that this class of pharmaceutical product (e.g., opioids) have a high risk of being diverted and a great propensity to cause harm when used improperly.

8.2 Group 2 Distributors

The Group 2 ("G2") distributors are large, national pharmacy or retail chains, which have embedded distribution operations that supply only their own pharmacies. Although pharmacies are part of the overall controlled substances "closed loop" system,[149] this review is focused on controlled substances compliance only in the context of those internal distribution operations.

While there is no uniformity among the G2 group regarding whether they distributed both Schedule II or Schedule III opioid medicinal products or just Schedule III products,[150] all group members ultimately

[149] *See* Discussion *infra*.

[150] For example, Walgreens internally distributed both Schedule II and III opioids, while CVS only handled Schedule III opioids internally.

outsourced the distribution of opioid products to their retail locations upon the reclassification of hydrocodone combination products ("HCPs") from Schedule III to Schedule II in October 2014.[151] After that date, opioid products were provided to G2 retail pharmacies via Group 1 ("G1") distributors sometimes augmented by other independent distributors serving as secondary suppliers.

Although the G2 distributors were like the G1 distributors in that profits trumped compliance, the G2 companies focused most of their anti-diversion efforts on protecting their retail pharmacy business. Consequently, the need for distribution centers to maintain reasoned, prudent and careful measures to prevent opioid diversion (e.g., a SOM program) which is expected of those handling prescription opioid medicines was treated as an afterthought, if it was recognized at all. Furthermore, distribution center anti-diversion efforts tended to focus on losses and thefts (e.g., loss prevention), rather than on whether they were shipping suspicious orders.

Again, even though applicable standards for corporate compliance and controlled substances anti-diversion programs were established in the early 1970s and 1990s respectively, it was not until the 2008-2009 timeframe that they undertook any meaningful efforts to meet their legal, regulatory and societal obligations. Nor did they make their controlled substances efforts part of their overall corporate compliance programs in a meaningful way.

The G2, for the most part, made only token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market and then only when the DEA directed them to. Thus, both companies failed to manifest good corporate responsibility by not undertaking the reasoned, prudent and careful measures expected of those handling prescription opioid products. For example, although all the G2 distributors had ready access to their own dispensing data, none of them tried to incorporate that information into their anti-diversion programs.

In addition, since retail pharmacies represent a significant profit center for the G2 group, those internally who were charged with controlled substances compliance invested substantial time and resources trying not to classify excessive pharmacy orders as "suspicious," so as not to disrupt product supply. This constituted an inherent conflict of interest that elevated profits over compliance. In short, throughout the review period, the G2 distributors failed to act responsibly to undertake the reasoned, prudent and careful measures expected of those handling prescription opioid products even while acknowledging that there was an exponential increase in opioid usage.

On the compliance maturity and program effectiveness scale, the G2 companies are barely starting into the foundational level, and while the model does not have a remedial level, if it did, that is where they would be found. Their behavior is unreasonable given the fact that they understood that (a) opioid products have a high risk of being diverted and a great propensity to cause harm when used improperly and (b) they simultaneously occupied two positions in the "closed loop" system (e.g., dispenser and distributor).

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[151] *See* 79 Fed. Reg. 49661 (Aug. 22, 2014).

8.3 Manufacturer Group

Although only one manufacturer was examined in this review (Mallinckrodt) given its market presence, I believe that it is possible to compare the anti-diversion efforts of manufacturers and distributors. From 1996 to 2017, Mallinckrodt was a leading manufacturer of generic opioid products, selling over $18 billion in opioid products.[152] For Summit and Cuyahoga Counties, Mallinckrodt via one of its subsidiaries was the largest supplier of opioid products. Thus, between 2006-2014, Mallinckrodt shipped more opioid products – 26.7% of the total or 2,363,328,618 MMEs – than any other manufacturer.[153]

For manufacturers, while the anti-diversion and corporate compliance standards are the same, as well as many of the controls (e.g., thresholds, due diligence, qualifying new customers, etc.), a manufacturer's anti-diversion program is geared towards looking at the distributor's customers, for which it has access to a large amount of information, in order to assure itself that the distributors are taking the necessary steps to avoid providing opioid products to pharmacies engaging in diversionary behavior.

In the same vein, the issues seen with Mallinckrodt's anti-diversion efforts mirror those seen with both the G1 and G2 distributors. First, even though the applicable standards for controlled substances and corporate compliance were established in the early 1970s and 1990s respectively, Mallinckrodt did not apply serious efforts to establish a credible anti-diversion program until 2008.

Second, as was seen with both the G1 and G2 distributors, Mallinckrodt was determined to only do the bare minimum as expressed by the DEA, which resulted in token efforts to implement a compliance program to detect and prevent the shipment of prescription opioid products into an illicit market, let alone to fulfill the required legal and regulatory obligations. Mallinckrodt, in so doing, failed to manifest good corporate responsibility by not undertaking the reasoned, prudent and careful measures expected of those manufacturing and selling opioid products.

Third, like all the distributors examined, Mallinckrodt designed, implemented and operated its SOM program in such a manner as to avoid classifying customer orders as "suspicious" in order to avoid having to stop suspect opioid shipments to customers. Even after the DEA provided Mallinckrodt with explicit directions such as "'If you think it is suspicious, don't fill it,'"[154] Mallinckrodt selectively interpreted those explicit directives in such a manner so as not to impact its continued distribution of opioid products, although doing so rendered its anti-diversion program ineffective. Thus, Mallinckrodt repeatedly failed to make the necessary changes to its anti-diversion practices in order to achieve a robust and effective compliance function in accordance with the values, principles and societal expectations for those involved in distributing prescription opioids. Also, when confronted with objective evidence of inappropriate opioid ordering, Mallinckrodt still did not make reasonable inquiries as to "why" this ordering was occurring. By doing so, Mallinckrodt studiously avoided having to address customer behaviors it knew or should have known were inappropriate and likely diversionary.

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[152] *See* January 30, 2019 Mallinckrodt Response to Interrogatory No. 33 & Ex. E.

[153] See Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, ¶ 13 & Table 1 (April 15, 2019).

[154] *See* Email from B. Ratliff to J. Rausch, *et al.*, Suspicious Order Monitoring, (Apr. 1, 2008) (Karen Harper was copied on this email), MNK-T1_0000268860.

Finally, comments by company employees such as opioids are 'just like Doritos; keep eating, we'll make more'"[155] exemplify that although Mallinckrodt espoused company values of being patient-centric and operating with integrity, these values were platitudes. The previous comments also show that Mallinckrodt apparently was indifferent to any negative societal impact flowing from its actions. Consequently, while Mallinckrodt publicly stated that this behavior "is antithetical to everything that Mallinckrodt stands for and has done to combat opioid abuse and misuse,"[156] Mallinckrodt's current Chief Commercial Officer and previous President of the company's generics division, also repeatedly refused under oath to express any opinions about the behavior, let alone condemn it as being "antithetical" to Mallinckrodt's corporate values.[157]

As a result of all the issues highlighted above, on the compliance maturity and program effectiveness scale, Mallinckrodt's program falls at the extreme lower end of the foundational level.

8.4 An Integrated Ecosystem

The DEA "closed loop" system for the distribution of opioid products is no different from a biological ecosystem in which each group ("species") has a distinct role to play, and if a group or even some members of that group fails to perform their allotted role, the foundation of the ecosystem is threatened.

As previously discussed, distributors and manufacturers both play a role in the controlled substances ecosystem. For the review period, based upon the individual company information I reviewed, the companies reviewed here did not maintain and operate the type of anti-diversion programs that are expected of prudent and socially responsible companies handling this type of high-risk product.

Furthermore, manufacturers and distributors also are corporate-entities focused on shareholder return. As such, there is limited incentive for each to use the information which it has access to, either to enhance its own controlled substances compliance program or to share information about improper pharmacy behavior with others in the opioid supply chain. Thus, a predictable outcome of the failure of manufacturers and distributors to maintain an effective anti-diversion program is that it allows opioid product dispensers (i.e., retail pharmacies) to use the weaknesses in each company's program to their advantage to maintain a consistent, dependable supply of opioid products to meet physician and patient (i.e., customer) demand whether legitimate or not.

Therefore, because the "closed loop system" is an ecosystem, any examination should look at the operation of the full ecosystem as well as the individual parts. Euclid Family Pharmacy and CVS stores 3322 and 4800 provide excellent examples to do so.

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[155] *See* Associated Press, *Suit: US Drug Agency Deemed Firm 'Kingpin' in 'Drug Cartel*,' THE NEW YORK TIMES (Apr. 1, 2019), https://www.nytimes.com/aponline/2019/04/01/us/ap-us-opioid-lawsuit-tennessee html.

[156] *Id.*

[157] *See* Hugh O'Neill Deposition, 152:15-153:4; 155:23-158:15; 166:10-169:15; 171:10-175:19 (Mar. 13, 2019).

A. Euclid Family Pharmacy

Located in Cuyahoga County Ohio, the Euclid Family Pharmacy sits in the lobby of a medical building that serves a suburb of Cleveland with a population of approximately 50,000 people.[158] Since 1995, Euclid has been owned and operated by Timothy Williams, a licensed Ohio pharmacist.

As a result of being in the medical building, a significant portion of Euclid's business comes from the pain clinics co-located in the building.[159] As a result of Euclid's advantageous location, pharmaceutical manufacturers have long targeted Euclid for its opioid product sales potential.

For example, in 2006, Endo Pharmaceuticals listed Euclid as one of the "high opioid potential" pharmacies in the region.[160] That list was circulated to Endo's sales representatives with specific instructions about how they could leverage key information about physicians, pharmacies, and distributors to maximize opioid product sales. Endo specifically instructed its representatives to ask physicians "to assist your stocking effort by sending a note or making a call to the pharmacy that they send their patients to fill their opioid prescriptions." Endo also instructed the representatives to follow up with pharmacies "to ensure that the drug is ordered." and to "inquire as to who is the primary wholesaler and back-up wholesaler the pharmacy uses and record that information for your information at a later time."[161]

Purdue Pharma L.P., engaged in a similar effort in 2008 as it launched a new promotional program for OxyContin.[162] The Purdue program allowed customers to redeem OxyContin Savings Cards, which had the effect of increasing the period of time a patient would use the drug.[163] Euclid Pharmacy was one of the pharmacies which participated in the OxyContin Savings Card program, and by 2009, the effects were evident as Purdue's sales of oxycodone and hydrocodone notably increased.[164] Although the sales increases are notable on their own, the increases are more troubling when weighed against the fact that in 2006, Mr. Williams told a reporter for that he believed OxyContin was more addictive than other prescription opiates.[165]

During this time, AmerisourceBergen, one of Euclid Pharmacy's controlled substances distributors, was repeatedly releasing orders for OxyContin and Endocet that exceeded its internal suspicious order monitoring thresholds.[166] However, in 2013, Euclid switched to McKesson as its primary distributor.[167]

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[158] *See* Robert Iuzzolino, *McKesson Controlled Substances Monitoring Program Regulatory Investigative Report - Euclid Pharmacy*, 3 (Apr. 28, 2018), MCKMDL00647803; McKesson Euclid Pharmacy #66729 Due Diligence File, MCKMDL00555714.

[159] *Id.*

[160] Endocet is the brand name for the combination of oxycodone and acetaminophen.

[161] *See* Email from Chris Speaker to Teresa Leigh, Pharmacy Calls, (Aug. 25, 2006) (enclosing an email from Mike Weber to All Pharma Representatives) ENDO-OPIOID_MDL-02776076.

[162] OxyContin is a controlled release version of oxycodone that Purdue manufactured. OxyContin is the brand name.

[163] See https://www.wbur.org/commonhealth/2019/02/01/purdue-oxycontin-savings-cards (last visited March 25, 2019).

[164] *See* Spreadsheet, March 2009 OxyContin Savings Cards Redemption, PPLPC004000194244; ABDCMDL00170149.

[165] See Purdue News Clips Report, (undated), PPLPC039000161600 at PPLPC039000161640.

[166] *See* AmerisourceBergen Spreadsheet, Legacy Threshold Override Report for Multiple Customers of Ohio from 01/01/2007 to 12/31/2012, ABDCMDL00279831; AmerisourceBergen Spreadsheet, CSRA Comment Report Request for all Opioid Items from Cuyahoga County, OH, ABDCMDL00279842; Email from ABC Notification to ColumbusOMP, NO-Reply Notification on Items in

McKesson's original new pharmacy questionnaire was completed in February 2013 and indicated that many of Euclid's opioid patients spoke little English and were on Medicare/Medicaid or worker's compensation. Euclid also was associated with a local healthcare and pain management clinic and most of its patients were coming from a doctor's office or clinic in the building.[168] McKesson estimated that Euclid dispensed 10,000 dosage units per month of oxycodone and 5,000 per month of hydrocodone.[169] The diligence file contains Mr. Blaine Snider's signature under the Regulatory Review block, but contains no Director of Regulatory Affairs sign-off.[170] Hence, the original customer questionnaire was incomplete, as it does not indicate the required Director of Regulatory Affairs review occurred.

Later in October 2013, during a review of Euclid, Joe Lumpkin, McKesson's RA Regional Director, noted that Euclid had purchased an average of 16,230 dosage units of oxycodone per month for the preceding 3 months (the threshold was set at 16,300).[171] Mr. Lumpkin raised specific concerns about Euclid's oxycodone purchases noting that they comprised 49.7% of Euclid's overall controlled substances purchases and were more than double the average for that geographic area, which was 22.4%.[172] Consequently, Mr. Lumpkin concluded Euclid's new threshold for oxycodone should be reduced to 6,500 dosage units per month.

However, that proposed reduction never occurred. By December 2013, Euclid's oxycodone thresholds instead were increased to 18,000 dosage units per month or 1,700 dosage units above the original threshold.[173] Therefore, despite Mr. Lumpkin's analysis showing Euclid continued to order exceedingly high amounts of oxycodone when compared to other controlled substances, McKesson increased Euclid's thresholds even further. Thus, the company continued to allow these above average purchases rather than take the required concrete steps to address the potential diversion, even when faced with new "red flag" evidence. For example, [redacted]

Investigation for Threshold violation – APPROVED COMPLIANT CUSTOMER, (Oct. 31, 2008), ABDCMDL00331149; Email from ABC Notification to ColumbusOMP, NO-Reply Notification on Items in Investigation for Threshold violation – APPROVED COMPLIANT CUSTOMER (Dec. 26, 2008), ABDCMDL00331154.

[167] *See* Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated Mar 25, 2019 at 318 (Oxycodone Distribution to Euclid Family Pharmacy).

[168] *See* Euclid Due Diligence File (Feb. 15, 2013), MCKMDL00555714 to MCKMDL00555732

[169] *Id.*

[170] *Id.*

[171] *See* Email from Joe Lumpkin to Andrew Moore, *et al*., Euclid Family Pharmacy, (Oct. 7, 2013), MCKMDL00566034.

[172] *Id.*

[173] *See* Threshold Change History Report, MCKMDL00675596.

[174] *See* Robert Iuzzolino, *McKesson Controlled Substances Monitoring Program Regulatory Investigative Report - Euclid Pharmacy*, 5 (Apr. 28, 2018), MCKMDL00647803.

By working with both ABC and McKesson, Euclid was able to get a consistently large monthly supply of oxycodone (at least 10,000 dosage units per month) from January 2006 to January 2018.[175] Thus, Euclid took advantage of the holes in the compliance programs for both distributors over that time period to obtain suspiciously high amounts of opioids that was not confirmed to be legitimate by either distributor.

B. CVS Store 3322

CVS Store 3322, located on Brookpark Road in Cleveland (Cuyahoga County), Ohio, ordered and received high-volumes of oxycodone from Cardinal Health and hydrocodone from CVS' own distribution centers from 2006 to 2014.[176]

In the case of oxycodone, CVS 3322's volume began at 313,500 dosage units in 2006 (an average of 26,125 per month, to an all-time high of 648,300 dosage units in 2012 (an average of 54,042 per month).[177] The 2012 level was only slightly reduced to 422,200 dosage units in 2014 (an average of 35,183 per month), and still exceeded the 2006 levels by more than 25%.[178]

Similarly, for hydrocodone, CVS 3322's volume began at 349,200 dosage units in 2006 (an average of 29,100 per month) to a maximum of 476,200 dosage units in 2011 (an average of 39,683 dosage units per month). However, CVS 3322 was double-dipping and ordering some of its hydrocodone supply (between 2 and 3%) from Cardinal during the same time period.[179]

Despite these high volumes of opioid purchases, neither Cardinal nor CVS appears to have adequately monitored this store or conducted appropriate investigations. The limited due diligence file produced by Cardinal begins in 2012 with an extremely limited due diligence memorandum located in the file.[180] Beyond the basic facts and figures in the file, Cardinal conducted several "site surveillance visits" from 2014 to 2017.[181] These site surveillance visits were not the same as onsite visits and consisted primarily of observing the pharmacy from afar (e.g., looking for out-of-state license plates).[182] Cardinal also did a single one-hour site

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[175] *See infra* at Appendix A, Figure 2.

[176] *See* Memorandum from D. Roberts to File, OHIO CVS STORES LLC #3322 2007 BROOKPARK RD, CLEVELAND, OH 44109, 2 (Jul. 15, 2016) (Noting Cardinal was supplying all the store's Schedule II controlled substances needs and was the back-up distributor for Schedule III-IV controlled substances.), CAH_MDL2804_00000216.

[177] *See* Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated Mar 25, 2019 at 1944-1945 (Opioid Shipments to AR7531418 by Distributor (2006-2014)).

[178] *Id.*

[179] *See id.*

[180] *See* Memorandum from N. Rausch to File, CVS #3322 (DEA # AR7531418), (Jul. 17, 2012), CAH_MDL2804_00000204. However, there are records showing that CVS 3322 was purchasing from Cardinal as early as July 2007. *See* Cardinal Health Compliance Group, *Ingredient Limit Report*, (undated) (Showing orders in July 2007), CAH_MDL_PRIORPROD_DEA07_01120515 at 011208813-011208814.

[181] *See* Cardinal Health, Surveillance Site Visit Report, (Jan. 24, 2014), CAH_MDL2804_00000207; Cardinal Health, Surveillance Site Visit Report, (Apr. 13, 2015), CAH_MDL2804_00000212; Cardinal Health, Surveillance Site Visit Report, (May 16, 2017), CAH_MDL2804_00000215.

[182] *See* Stephen Forst Deposition, 30:4-33:19 (Jan. 22, 2019) (Mr. Forst was a Director in the Quality and Regulatory Affairs Department with anti-diversion responsibilities).

visit to the store in June 2012.[183] Neither the 2012 site visit nor the subsequent site surveillance visits noted any "red flags." However, the way the visits were conducted (e.g., short duration or scope) they were of limited utility to detect diversion.

CVS, on the other hand, does not appear to have performed due diligence with respect to the high volume of HCPs shipped to this store, until May 2014.[184] Therefore, because neither Cardinal nor CVS performed adequate due diligence on the store, the pharmacy was able to purchase large volumes opioids uninterrupted from 2006 to 2014.

C. CVS Store 4800

CVS Store 4800 located at 590 East Market Street in Akron (Summit County), Ohio also ordered and received high-volumes of oxycodone from Cardinal Health and hydrocodone from CVS' own distribution centers from 2006 to 2014.[185]

CVS 4800's oxycodone received from Cardinal Health ranged in volume from 213,200 dosage units in 2006 (a monthly average of 17,667) to a high of 536,600 dosage units in 2013 (a monthly average of 44,716).[186] For hydrocodone, the volumes ranged from 257,500 dosage units in 2006 (a monthly average of 21,475) to a high of 450,100 dosage units in 2009 (a monthly average of 37,508).[187] However, CVS 4800 was double-dipping and ordering some of its hydrocodone supply (between 2 and 19%) from Cardinal from 2006 to 2014.[188]

The Cardinal due diligence file for CVS 4800 contains an undated questionnaire. Cardinal also conducted a single one-hour site visit to the store in June 2012[189] and two surveillance site visits in January 2014.[190] However, none of the visits noted any "red flags." Furthermore, as in the case of CVS 3322, the way all three visits were conducted (e.g., short duration or scope) they were of limited utility to detect diversion. In the case of CVS, although this store did flag on the Item Review Reports, there was no documentation found demonstrating that diligence was performed by CVS with respect to these high-volume purchases.[191] Therefore, because neither Cardinal nor CVS performed adequate due diligence on the store, the pharmacy was able to purchase large volumes opioids uninterrupted from 2006 to 2014

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[183] *See* Cardinal Health, Report of Investigation, (Jun. 11, 2012), CAH, MDL2804_00000205.

[184] *See* CVS Health, Orders of Interest SOM-3724010, (May 5, 2014), CVS-MDLT1-000007490.

[185] *See* Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated Mar. 25, 2019 at 3216-3217. (Opioid Shipments to BR0287234 by Distributor (2006-2014)).

[186] *Id.*

[187] *Id.*

[188] *Id.*

[189] *See* Cardinal Health, Report of Investigation, (Jun. 11, 2012), CAH, MDL2804_00000688. Both site visits for CVS 3322 and 4800 were conducted on the same day.

[190] Cardinal Health, Surveillance Site Visit Report, (Jan. 20, 2014), CAH_MDL2804_00000692; Cardinal Health, Surveillance Site Visit Report, (Jan. 24, 2014), CAH_MDL2804_00000690;

[191] *See* CVS, Item Review Report, (Jan. 4, 2011), CVS-MDLT1-000101092; CVS, Item Review Report, (Mar. 1, 2011), CVS-MDLT1-000101174; CVS, Item Review Report, (Mar. 29, 2011), CVS-MDLT-000101371.

PART V: Individual Company Reviews

9 McKesson Corporation

9.1 Background

Founded in 1833, McKesson Corporation ("McKesson") describes itself as "the oldest and largest healthcare company in the nation, serving more than 50% of U.S. hospitals and 20% of physicians."[192] The company also claims to "deliver one-third of all medications used daily in North America."[193] Within the U.S., McKesson currently operates 27 distribution centers registered with the DEA to handle controlled substances.[194] From 2009 to 2018, the number of McKesson employees grew from some 32,500 employees to 78,000.[195]

McKesson's controlled substances program can be characterized as having four distinct phases, which also correspond to the three different SOM programs McKesson employed. The first phase covers the period before May 2007, when McKesson's program operated under Section 55 of the Drug Operations Manual. The second phase covers the introduction of the Lifestyle Drug Monitoring Program ("LDMP"). The third phase covers the

[192] *See* MCKESSON CORPORATION, https://www.mckesson.com/ (last accessed Nov. 27. 2018).

[193] *Id.*

[194] McKesson Corporation, *Board of Directors' Response to International Brotherhood of Teamsters*, 1, P1.082 (April 20, 2018) at https://www.mckesson.com/about-mckesson/newsroom/press-releases/2018/mckesson-board-releases-findings-and-recommendations-of-independent-investigation/ [MCK Teamsters Response].

[195] *See* STATISA, *Number of employees at the McKesson Corporation from 2009 to 2018,* https://www.statista.com/statistics/240011/employment-at-the-mckesson-corporation/ (last accessed Dec. 6, 2018).

Controlled Substances Monitoring Program ("CSMP"), the successor to the LDMP, which was implemented as a result of the 2008 settlement with the DEA and periodically revised during the time period from 2008 to 2017.

With the 2017 settlement and the detailed obligations in the Compliance Addendum, McKesson's controlled substances compliance program entered a new fourth phase.

9.2 Executive Summary

My review of McKesson's controlled substances compliance efforts from 1996 to the present reveals a consistent pattern of systemic failures to meet its regulatory and corporate governance obligations with respect to controlled substances. Poor design exacerbated by poor implementation resulted in a series of "paper programs" that were neither effective for controlling diversion nor in identifying and reporting suspicious orders of controlled substances.

The root cause of this systemic failure largely comes down to corporate culture. McKesson's controlled substances compliance efforts did not have the support and commitment of McKesson's senior management and its Board of Directors. Despite the well-documented existence of the applicable compliance program standards for controlled substances and corporate compliance dating back to the 1970s and 1990s respectively, which McKesson management was aware of, McKesson did not attempt to implement effective compliance programs for either controlled substances or corporate compliance until many years later.

Furthermore, McKesson has twice settled with the DEA for the company's inability to "maintain ... effective controls against diversion of particular controlled substances," and it's failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances"[196] These settlements occurred in spite of repeated signals to McKesson and its management of the company's obligations with regards to the CSA and acknowledgements by those in the position to judge "what good looked like" that its controlled substances compliance program was inadequate. McKesson's management simply did not act unless it was pushed to do so by the DEA, and even then, the company only did the minimum to avoid further scrutiny.

9.3 Impact

The impact of McKesson's failure to maintain an effective compliance program can be seen in Summit and Cuyahoga County. Based on an analysis done using McKesson's own data, during the period from 2006 through mid-2008, no suspicious orders in either county were stopped or reported to DEA by McKesson.[197] This is in stark contrast to mid-2008 through the end of July 2013 when McKesson flagged 517 and 481 threshold excursions for pharmacies in Summit and Cuyahoga counties respectively.[198] Even so, McKesson

[196] *See* Administrative Memorandum of Agreement between United States Department of Justice, Drug Enforcement Administration and McKesson Corporation at 2 (Jan. 17, 2017), MCKMDL00355349 ["2017 AMOA"].

[197] *See* Analysis of Cuyahoga and Summit County Threshold Breaches & DEA SOM Reports from January 1, 2006 to July 31, 2013, MCKMDL00478912.

[198] *Id.*

made no suspicious order reports to the DEA involving any of 998 flagged orders in those two counties. .[199] This is despite the fact that in 2015, while negotiating with the DEA and moving towards its second settlement, McKesson reported on average 6.6 suspicious orders per customer to the DEA during that single year alone.[200]

As a result, various retail pharmacies obtained high levels of opioids with little or no investigation or interrogation. Below are a few illustrative examples.

Acme Pharmacy #30

Acme Pharmacy #30 was located in Summit County, Ohio and in 2015 was one of 17 pharmacies owned and operated by Acme Fresh Markets, a local grocery store chain.[201] Acme #30 was unique among the other pharmacies in the chain because it was not located inside a grocery store, but instead was situated on the first floor of the Akron General Hospital medical building. This same medical building also housed the Summit Pain Specialists, a local pain management clinic.[202]

Concerns about the Summit Pain Specialists itself began in June 2011 when McKesson began receiving reports that the physicians at Summit Pain Specialists were seeing a large number of patients, but that the clinic was not staffed appropriately to provide proper treatment to them.[203]

In early December 2012, McKesson's Denise Josyln notified Acme's Director of Pharmacy, Joseph M. Lahovich that Acme #30 was approaching its oxycodone threshold of 16,000 dosage units per month[204] to which he responded that Acme #30 needed its threshold increased to 70,000 dosage units per month to meet the needs of Summit Pain Specialists.[205] To put that request in context, Acme was looking for an annual threshold of 840,000 dosage units of oxycodone when the 2012 national annual average was 75,584 dosage units.[206] Thus, Acme wanted its annual threshold set at more than 11 times the national average. That request alone should have triggered a suspicious order report, but it did not.[207]

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[199] *Id.*

[200] *See* Appendix C: McKesson Key Facts and Figures. Formula used: 230,000 (2015 SORs) / 34,816 (customers) = 6.6 SORs per customer.

[201] *See* M. Oriente, McKesson's Controlled Substance Monitoring Report – Acme Fresh Markets Pharmacy #30 (Mar. 2, 2015) (This was a customer site visit.), MCKMDL00402074 ["Acme #30 Site Visit"].

[202] *Id.*

[203] *See* Email from M. Oriente to B. Snider, RE: Summit Pain Specialists (Jun. 2011), MCKMDL00634936; *see also* Email from J. Kuczynski to P. Soos, *et al.* RE: New Pharmacy/Stowe, OH (Nov. 4, 2010), MCKMDL00492227.

[204] *See* Email form D. Joslyn to J. Lahovich, *et al.*, Re: CSMP-Acme (Dec. 5, 2012), MCKMDL00627001.

[205] *See* Email from J. Lahovich to D. Joslyn, *et al.*, Re: CSMP-Acme (Dec. 6, 2012), MCKMDL00627001. In 2010, McKesson Regulatory Affairs raised concerns about Summit Pain Specialists and their volume of prescriptions. *See* D. Gustin to K. Diemand, *et al.*, *RE: New Pharmacy/Stowe, OH* (Nov. 2, 2010), MCKMDL00492227.

[206] *See* McKesson presentation, *Understand ARCOS Data*, 1 (Feb. 24, 2014), MCKMDL00430387. McKesson's annual average was 98,000 dosage units. *See* McKesson Regional Statistical Norms, 2 (Feb. 24, 2014), MCKMDL00430387.

[207] *See* Cuyahoga and Summit County Threshold Breaches & DEA SOM Reports from January 1, 2006 to July 31, 2013, MCKMDL00478912.

Ms. Joslyn submitted the request to Michael Oriente the DRA who did not approve the full request, but told her to:

> submit a threshold change for a 25% increase. A 70,000-dose threshold is more than most of our customers. This account will be under Joe Lumpkin out of New Castle he will have the final say. I will approve a 25% for the month until Joe can get there for a visit for such a threshold review. We'll want the top 5 prescribers that are writing scripts that are being filled at this location and dispensing data minus any patient info for the last three months for all oxycodone base products.[208]

The TCR approval was granted the same day it was submitted with no record that Mr. Oriente reviewed any additional information before granting the 25% increase. Nor does it appear that any site visit was conducted before March 2015.

In January 2013, Acme again requested its threshold be increased to 70,000 dosage units per month for oxycodone[209] , and this time it was granted.[210] Once more it was granted without documentation to support the request. From June 2014 through December 2014, Acme received between 63,800 to 70,000 dosage units of oxycodone per month.[211] Within that period, 89% of the prescriptions filled by Acme were written by physicians at Summit Pain Specialists.[212]

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[208] *See* Email from M. Oriente email D. Joslyn, *et al.*, RE: CSMP-Acme (Dec. 6, 2012) (Blaine Snider and Joe Lumpkin are copied on this email), MCKMDL00627001.

[209] *See* Email from J. Lahovich to D. Joslyn, *et al.*, Acme 1/11/13 CSMP (Jan. 14, 2013), MCKMDL00496271.

[210] *See* McKesson, Acme Oxycodone Threshold History Report 2012 to 2015, P1.1907; *see also* Acme #30 Site Visit at MCKMDL00402076.

[211] *Id.*

[212] *See* Acme #30 Site Visit at MCKMDL00402074.

The New Castle Distribution Center

McKesson has identified the New Castle Distribution Center as its facility that shipped more than 99% of the opioid products to retail pharmacy customers in both Summit and Cuyahoga Counties.[213] Therefore, this Distribution Center's due diligence practices regarding suspicious orders, are particularly relevant to my analysis. Below, I discuss in detail two specific pharmacies serviced by the New Castle Distribution Center.

Franklin Pharmacy

Franklin Pharmacy located in Warren, Ohio is in a county adjacent to Summit and Cuyahoga Counties.[214] Over a period of more than six years, Franklin was permitted to order extraordinarily high numbers of opioids by McKesson.

On January 26, 2009, Franklin requested to increase its monthly oxycodone threshold from 50,000 to 70,000 dosage units and requested to increase its hydrocodone monthly threshold from 35,000 dosage units to 45,000 dosage units.[215] This request was granted, noting the pharmacy's relationship with local and regional pain clinics and that the pharmacy had reportedly brought over some purchases from another distributor to McKesson.[216] No evidence was presented that McKesson had in fact verified the pharmacy's relationship with these pain management clinics or its transfer of purchases from another distributor to McKesson.[217]

In April 2013, McKesson noted that Franklin Pharmacy had exceedingly high ratios of controls to overall prescription purchases and oxycodone to overall prescription purchases, an indicator of diversion activities according to McKesson's CSMP. However, there is no indication that McKesson conducted any further due diligence even though a site visit was recommended.[218]

Two years later, in May 2015, McKesson finally conducted the recommended site visit, which concluded "the pharmacy posed an unacceptable risk to McKesson and recommended that the sale of controls to the pharmacy be terminated."[219] Despite being considered an unacceptable risk, the May site visit results were not finalized until August 2015, almost 90 days after the site visit concluded.[220]

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213 McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests at 10, In Re National Prescription Opiate Litigation, Case No. 18-OP-45132 (N.D. Ohio).

214 *See* McKesson Pharmacy Questionnaire, (May 18, 2015), MCKMDL00554545 at MCKMDL00554548.

215 *See* Franklin Pharmacy Threshold Change Form, (Jan. 26, 2009), MCKMDL00540065 at MCKMDL00540068.

216 *Id.*

217 [redacted]. *See* McKesson U.S. Pharmaceutical Regulatory Affairs, *ISMC Controlled Substance Monitoring Program Operating Manual*, 19, § 5.1.1 (Jun. 1, 2015), MCKMDL00330099. Although the list was not in existence in 2009, Franklin's response in 2009 should have been considered as a red flag when it was received in 2009.

218 *See* Email from B. Snider to J. Kuczynski, *et al.*, FW: Monthly Drug Usage Report – March, (Apr. 17, 2013) (showing that Franklin was purchasing 35.65% controlled substances to total prescription purchases and oxycodone constituted 31.25% of the total controlled substances purchased), MCKMDL00565981.

219 *See* Gary Davis, McKesson's Controlled Substances Monitoring Program Regulatory Investigative Report, Re: On-Site Review, Franklin Pharmacy, (Aug. 7, 2015), MCKMDL00554545 at MCKMDL00554563.

220 *Id.*

The site visit at Franklin Pharmacy found numerous diversion "red flags" including, but not limited to:

- A pharmacist for Franklin's had previously been suspended by the Ohio Board of Pharmacy for being "addicted to prescription drugs and stealing them from the pharmacy where she worked."[221]
- A very high ratio of controls to overall purchases[222];
- Data establishing it was the highest oxycodone dispenser among New Castle's customers[223]; and
- A clear pattern of frequent dispensing of the Holy Trinity drug cocktail.[224]

It was only after this visit that the customer was recommended for termination. However, much of the information obtained during this visit was generally available to McKesson for years during which Franklin was receiving unchallenged suspicious amounts of opioid products.

Martella's Pharmacy

Martella's Pharmacy in Johnstown, Pennsylvania was owned and operated by Joseph Martella.[225] On October 19, 2010, immediately after becoming a new McKesson customer, Martella's petitioned McKesson to increase its thresholds for several controlled substances, including oxycodone.[226] These increases were immediately approved and without any apparent due diligence: "Michael approved the TCR with no questions."[227] However, facing customer pressure and not satisfied with the approved increase, McKesson's sales representative, John Kuczynski exerted significant pressure to force McKesson Regulatory Affairs to increase the thresholds further writing:

> We need to adjust their number across the board. Please work with Michael to get this issue resolved. We can't be in a reactionary mode right now with them.[228]

However, this increase was not enough to satisfy Martella's and on October 22, 2010, Joseph Martella threatened to leave McKesson for "his old wholesaler because McKesson can't get his thresholds correct."[229] As a result, Mr. Kuczysnki once more stepped in insisting that Regulatory Affairs "make sure every effort is

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[221] *Id.* at MCKMDL00554564.

[222] *Id.* at MCKMDL00554567.

[223] *Id.* at MCKMDL00554567-68.

[224] *Id.* at MCKMDL00554570-71 ("The Holy Trinity" cocktail refers to the practice of combining an opioid, a benzodiazepine, and carisoprodol).

[225] *See* Indictment ¶2, U.S. v. Martella, Crim. No. 18-291 (W.D. Pa. 2018) ["Martella's Indictment"]. While located in Pennsylvania, the Martella's pharmacy goes to the heart of the New Castle Distribution Center's anti-diversion efforts and therefore by extension impacts Summit and Cuyahoga County customers that this distribution center serviced.

[226] *See* Email from Sharepoint to D. Nusser, *et al.*, Status of Threshold Change Request for Martella's Pharmacy (Conemaugh/Martella's), (Oct. 19, 2010), MCKMDL00489869 at MCKMDL00489870.

[227] *See* Email from D. Nusser to J. Kuczynski, RE: Status of Threshold Change Request for Martella's Pharmacy (Conemaugh/Martella's), (Oct. 19, 2010), MCKMDL00489869-70.

[228] *See* Email from J. Kuczynski to D. Nusser, RE: Status of Threshold Change Request for Martella's Pharmacy (Conemaugh/Martella's), (Oct. 20, 2010), MCKMDL00489869.

[229] *See* Email D. Curtis to J. Melvin, Account #861446 Account Name Martella's Pharmacy, (Oct. 21, 2010), MCKMDL00495740.

made to adjust their threshold levels prior to them hitting the 85% level to prevent" Martella's orders from being held.[230] However, Mr. Kuczynski's demand did not articulate any basis to justify these requested increases.

On October 25, 2010, the thresholds for methadone and hydrocodone were increased 20% again.[231] Again, there was no apparent due diligence conducted to support the increase, and Blaine Snider, the New Castle distribution center manager, approved the increases without any dispensing data and noted these levels were "about the highest I've ever done anyone."[232] Only one month later, Martella's hydrocodone thresholds were again increased by another 2,000 dosage units still with no apparent due diligence or dispensing data to support the increase.[233]

In December 2016, McKesson received a subpoena from DEA asking for information concerning Martella's Pharmacy.[234] McKesson noted at the time this subpoena was received that Martella's ratio of controlled substances to overall purchases was 21.17%, which was "above the mean for control RX in the New Castle DC."[235] In November 2018, Joseph Martella, the owner of Martella's was indicted on 109 counts related to the diversion of various controlled substances including hydrocodone, oxycodone, oxymorphone, and morphine.[236] The conduct leading to the indictment was noted to span from April 2011 to June 2016, the exact time period that Martella's was a McKesson customer.[237] Despite receiving the subpoena in 2016, McKesson continued to provide the pharmacy with opioids, which Mr. Snider confirmed in his deposition.[238]

9.4 Company Commitment – Compliance Culture, Organization & Resources

The data reviewed in this subsection, when taken together with the remainder of the report, demonstrates a consistent pattern of negative behavior by senior and junior management stretching over years. Therefore, I can only conclude that in the case of controlled substances, McKesson senior management was neither supportive of nor committed to complying with its obligations under the CSA, nor did they work to foster a true culture of compliance within the organization.

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[230] *See* Email from J. Kuczynski to M. Oriente, FW: Account #861446 Account Name Martella's Pharmacy, (Oct. 22, 2010), MCKMDL00495740.

[231] *See* Email from Sharepoint to D. Nusser, Status of Threshold Change Request for Martella's Pharmacy, (Oct. 25, 2010), MCKMDL00492040 at MCKMDL00492041.

[232] *See* Email from B. Snider to J. Kuczynski, RE: Status of Threshold Change Request for Martella's Pharmacy, (Oct. 26, 2010), MCKMDL00492040.

[233] *See* Email from D. Nusser to J. Kuczynski, FW: Status of Threshold Change Request for Martella's Pharmacy, (Nov. 23, 2010) ("New customer, still adjusting thresholds to accommodate purchases. Also there are 4 accounts under this DEA number … the number of scripts have increased for all 4 pharmacies."), MCKMDL00491355.

[234] *See* R. Iuzzolino, McKesson's Controlled Substances Monitoring Program Regulatory Investigative Report, Re: Customer Account Report (Government Contact), (Dec. 15, 2016), MCKMDL00340046.

[235] *Id.* at MCKMDL00340048.

[236] Martella's Indictment at Count 109.

[237] *Id.*

[238] *See* Blain Snider Deposition, 342:10-343:7 (Nov. 8, 2018)

9.4.1 McKesson's culture demonstrates a lack of commitment & support for complying with its controlled substances obligations.

Throughout the review period, McKesson repeatedly demonstrated that notwithstanding its assurances to the DEA that it took controlled substances compliance seriously, the opposite was true. In other words, McKesson failed "to walk the talk." Even McKesson's establishment of a Corporate Compliance program in the 2006 timeframe with the elevation of the General Counsel, Laureen Seeger to the role of Chief Compliance Officer, Executive Vice President, and General Counsel did little to change McKesson's behavior.[239] As outlined below, the Corporate Compliance function had little involvement with controlled substances compliance until the mid-2015 organizational changes. Even then the need to comply with the controlled substances requirements does not appear on the Corporate Compliance "radar screen" (see discussion below).

This lack of commitment and support, and the resulting poor culture of compliance regarding controlled substances can be seen in the multiple warnings McKesson received during the period from the DEA, as well as the two DEA settlements that occurred within ten years of each other.[240] Furthermore, prior to concluding each of its two government settlements, McKesson and the DEA had repeated contact, conversations and correspondence about the poor state of McKesson's controlled substances program.[241] Therefore, McKesson was well aware of the DEA's expectations with regards to anti-diversion and SOM programs, knowledge it shared with its employees on several occasions during the period.[242] However, McKesson failed to translate that awareness to fashion an effective controlled substances compliance program.

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[239] *See* Laureen E. Seeger, Executive Profile, BLOOMBERG, https://www.bloomberg.com/research/stocks/people/person.asp?personId=26521629&privcapId=92001 (last accessed Dec. 21, 2018); *see also* Michael Johnsen, McKesson names new general counsel and chief compliance officer, DRUGSTORE NEWS (Jun. 23, 2014) at https://www.drugstorenews.com/news/mckesson-names-new-general-counsel-and-chief-compliance-officer/. However, as discussed in the Addendum, McKesson was a late bloomer when it comes to corporate compliance, as many others in pharmaceutical industry had established their programs years earlier and some were even on their second-generation program.

[240] *See* Settlement and Release Agreement and Administrative Memorandum of Agreement between the U.S. Dept. of Justice, Drug Enforcement Administration and McKesson Corp. (May 2, 2008), MCKMDL00337001 ["2008 MOA"]; *see also* 2017 AMOA.

[241] *See* Memorandum from M. Mapes to J. Rannazzisi, *Internet Presentation with McKesson Corp. on September 1, 2005*, (Oct. 20, 2005), MCKMDL00496859; *see also* Memorandum from M. Mapes to J. Rannazzisi, *Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006*, (Jan. 23, 2006), MCKMDL00496876; *Summary of DEA-HDMA Mtg. on Suspicious Orders,* (Sept. 7, 2007), MCKMDL00574906; Letter from W. Ihlenfeld, II to G. Hobart, *Claims Against McKesson Corporation*, (Nov. 6, 2013), MCKMDL00409048; Letter from D. Cutteman, *et al*., to G. Hobart, *Registration Consequences for McKesson Corporation for Violations of the Controlled Substances Act*, (Nov. 4, 2014), MCKMDL00409453; Letter from W. Ihlenfeld, II to G. Hobart, *McKesson Matter – Ongoing Settlement Discussions*, (Mar. 20, 2014), MCKMDL00409174; Letter from J.F. Walsh to G. Hobart, *Possible Civil Action Against McKesson Corporation for Violations of the Controlled Substances Act*, (Aug. 13, 2014), MCKMDL00409224 at MCKMDL00409234; *see also* DEA 9/27/2006, 2/7/2007, 12/27/2007, 6/12/2012 Letters.

[242] *See* Presentation by D. Walker, *Lifestyle Drugs & Internet Pharmacies*, McKesson National Operations Conf., 4 (2007) (DEA Focus Slide lists what "DEA expects"), MCKMDL00403340 (Also stamped MCK-WVAG-003-0001335) [Walker Internet Presentation]; Denver Sales Mtg. presentation, *Controlled Substances Monitoring Program*, 5 (Mar. 10, 2008) ("Regulation ***has not*** changed, but the extent to which we are now required to monitor and provide stronger safeguards to ensure legitimate use of controlled substances ***has***." (Emphasis in the original)), MCKMDL00267635 at MCKMDL00267640 ["Denver Sales Meeting Presentation"]; *see generally,* Presentation by G. Boggs, *State of Prescription Drug Abuse*, (2013), MCKMDL00336833 ["Boggs Presentation"].

For example, in 2008 during the initial roll-out of McKesson's new Controlled Substances Monitoring Program ("CSMP"), the pharmacy program guide contained this message:

> McKesson values you and your business and is committed to working closely with you to ensure that your pharmacy continues to be successful. This program addresses the DEA's requirements to ensure controlled substances are used in the way they were intended, but **it also ensures that you as a McKesson customer can continue with business as usual**. (Emphasis added).[243]

Since the CSMP is ostensibly a program intended to control the inappropriate procurement of controlled substances, the statement is self-contradictory. A controlled substances compliance program, which meets the DEA's requirements, cannot allow every customer "to continue with business as usual." There will be some "suspicious orders" that will remain "suspicious" even after a complete investigation; orders that will go unfilled and be reported to the DEA in an effective program.

McKesson, however, went so far as to even instruct its employees in the CSMP manual to avoid using the word "suspicious" because "[o]nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substances sales to that customer must cease, and the DEA must be notified."[244] These statements demonstrate a cultural disconnect between McKesson's actual culture and a good compliance culture. This cultural disconnect was something the government too observed and commented upon in its correspondence with McKesson.[245]

After the 2008 government settlement and fine, this cultural disconnect did not improve. For example, it can be seen in the 2013 presentation made to McKesson management by Gary Boggs, former Special Agent, and Executive Assistant to the Deputy Assistant Administrator for the DEA's Office of Diversion Control. Mr. Boggs made this presentation prior to McKesson hiring him in November 2013 as a Senior Director of Regulatory Affairs.[246]

During his presentation, Mr. Boggs shared with those present what he termed "recurring comments" concerning controlled substances compliance apparently made to him during his tenure with the DEA. The comments shared with McKesson's management fall into two different but intertwined categories. First, there are the comments that appear to shift the blame for the registrant's non-compliant situation to the DEA because the DEA:

- Won't talk to us;
- Won't tell us what to do;

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[243] *See* Email attachment from D. Walker to Bill de Gutierrez-Mahoney, *McKesson Controlled Substances Monitoring Program – Program Guide for Pharmacies*, attachment p. 2 (Apr. 4, 2008), MCKMDL00543610.

[244] *See* McKesson, *McKesson Operations Manual for Pharma Distribution, Controlled Substances Monitoring Program*, 19 (Aug. 24, 2011), MCKMDL00000021 at MCKMDL00000039 ["CSMP Manual 2011"];

[245] *See* J.F. Walsh 8/13/14 letter to G. Hobart at 11 ("Our investigation has revealed a disturbing pattern. McKesson-Aurora's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders. We have identified this trend across several different areas."), MCKMDL00409224 at MCKMDL00409234.

[246] *See generally* Boggs Presentation. Mr. Boggs apparently made this presentation after leaving the DEA and before being hired by McKesson, although according to William De Gutierrez-Mahoney, Boggs had committed to joining McKesson. *See* W. De Gutierrez-Mahoney Deposition, 63:6-13 (Nov. 28, 2018).

- Won't tell us what to look for;
- Won't tell us who the suspicious registrants are;
- Won't approve our SOM system; and
- Won't share ARCOS data with us.[247]

Second, there are a series of statements, such as:

- The customer's registration is still valid so…;
- Why couldn't we have been warned first;
- We're too busy to look at everything; and
- If we don't sell it, our competitors will,

These statements demonstrate, at best, a lack of knowledge about or at worst a disregard for the need and importance of having strong internal controls governing the distribution of controlled substances.[248] In the case of McKesson, the narrative about the DEA not providing the company with enough direction to create an effective compliance program persists and has even been adopted by McKesson's Board of Directors.[249]

Additionally, despite statements to the DEA about McKesson's commitment to compliance,[250] McKesson neither adopted nor made enhancements to its controlled substances program voluntarily. Rather McKesson claimed to be surprised that significant outside pressures were being placed upon it by the DEA. As Executive Vice President and Group President, Paul Julien, to whom U.S. Pharma reported, wrote in early 2006 "I was surprised and very troubled that the DEA was considering issuing a show cause against that [the Lakeland, Florida] facility."[251]

In the same vein, both the 2008 and 2017 DEA settlements involved substantially the same issues,[252] and despite being under a settlement agreement with specific obligations to address the issues outlined in the 2008 settlement, McKesson failed to undertake the necessary program improvements and corrective actions to prevent the situation from recurring.[253] Rather, the company required the DEA in 2017 to spell out those necessary improvements in specific detail, which was memorialized in the mandated Compliance Addendum.[254]

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[247] See Boggs Presentation at 27.

[248] *Id*.

[249] *See* MCK Teamsters Response at 9 and 29.

[250] *See, e.g.,* Letter from P.C. Julian to J.T. Rannazzisi, 1 (Jan. 18, 2006) ("let me assure you and DEA that McKesson is committed to a compliance program that ensures the safe distribution of health care products, especially controlled substances.") MCKMDL00571360 at MCKMDL00571361.

[251] *See id.*

[252] *See* 2017 AMOA at 2 ¶¶ 6-7 and 3 ¶2.

[253] *Id.* at 3 ¶2 ("McKesson acknowledges that, at various, times during the period from January 1, 2009 up through and including the Effective Date of this Agreement . . . it did not identify or report to DEA certain orders placed by certain pharmacies that should have been detected by McKesson as suspicious based on the guidance contained in the DEA letters [referring to the Rannazzisi letters]."); *see also* 2017 AMOA at 4 ¶¶ 3b-3f.

[254] *See generally,* Compliance Addendum to Administrative Memorandum of Agreement between United States Department of Justice, Drug Enforcement Administration and McKesson Corporation at 2 (Jan. 17, 2017) MCKMDL00355416 ["MKC Compliance

McKesson's approach to compensating its sales force also is indicative of the company's lack of support for anti-diversion efforts. Although the sales force was assigned specific and important responsibilities under the CSMP, their compensation plan was not aligned with those expectations thereby undermining the effectiveness of the anti-diversion program. From the earliest days of the CSMP, sales representatives were assigned an integral role in McKesson's anti-diversion program. For example, the September 2008 version of the CSMP, tasked sales representatives with several important due diligence tasks including:

- Providing reasoning behind sales that prompted a level 1 review following a threshold excursion;[255]
- Introducing customers to the requirements of the CSMP;[256]
- Assisting in the completion of customer questionnaires, including collecting dispensing data and conducting on-site physical inspections;[257] and
- Assisting in the completion of customer interviews.[258]

There are two facets of this misalignment. First, the compensation plan for McKesson sales representatives until mid-2012 included opioid sales in the product mix.[259] While compensation plans based on product sales are not *per se* wrong, in McKesson's case because there was no countervailing incentives for reporting suspicious customer orders and activity and undertaking the CSMP duties assigned to them, McKesson put a system in place that clearly valued sales and revenue above compliance and corporate responsibility.

Thus, until 2012 McKesson's sales representatives had a direct financial incentive for their customers to purchases opioids and other controlled substances, but McKesson never offered any financial or performance incentives to the sales force for reporting suspicious customer activity as it related to controlled substances or their duties under the CSMP.[260]

All of this is consistent with the point raised to McKesson's outside counsel in 2014 by the U.S. Attorney for the District of Colorado, who wrote "[o]ur investigation has revealed a disturbing pattern. McKesson-Aurora's

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Addendum"]. Although this analysis focused on controlled substances compliance, McKesson adopted a similar approach towards its corporate compliance obligations. Despite a clear mandate from the FSGs in 1991 onwards, as well as the OIG in 2003 and the ACA in 2010, McKesson only established its corporate compliance program in 2006.

[255] *See* McKesson Operations Manual, *Controlled Substance Monitoring Program*, 7, § 2.2.2 (Sept. 6, 2008), MCKMDL00533239 at MCKMDL00533246.

[256] *Id.* at 8, § 3.1.

[257] *Id.* at 9 § 3.2.

[258] *Id.* at 13 § 3.3.

[259] *See* Presentation by McKesson Corporation to DEA, U.S. Pharmaceutical Controlled Substances Monitoring Program, 19 (Dec. 17, 2014), MCKMDL00409483.

[260] *See* Gene Cavacini Deposition, 127-180 (Jan. 25, 2019) (Discussing sales compensation plans for FY 2007 to FY 2013 and the lack of compliance measures.).

desire for increased sales and retaining its customers overrode its obligations to report suspicious orders. We have identified this trend across several different areas."[261]

9.4.2 McKesson's contention that the SOM requirements were too vague for it to design & operate an effective SOM program is specious.

While McKesson has repeatedly argued that the standards surrounding a SOM program were unclear because of incomplete guidance from the DEA, that position simply does not track with the information I reviewed.[262] Just by reviewing the DEA regulations and general guidance letters provided to all registrants during the period, it is possible to get a clear concept of what a successful SOM program should look like.[263] However, in addition to the publicly available information, McKesson received direct, non-public feedback from the DEA over a period of years.[264] Finally, as a member of the Healthcare Distribution Management Association ("HDMA"), McKesson participated in and had access to the Association's voluntary industry guidelines, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," which also provides clear direction on what a credible SOM program should look like.[265]

McKesson also understood that SOM programs are not static, but instead are meant to evolve as circumstances change.[266] Consequently, McKesson's assertion that it did not have enough information to construct and operate an effective SOM program demonstrates the company's lack of commitment to effective controlled substances compliance.

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[261] *See* J.F. Walsh 8/13/14 letter to G. Hobart at 11.

[262] The D.C. Circuit recently rejected this argument in *Masters Pharmaceuticals, Inc. v. DEA*, 15-1335 (D.C. Cir. 2017).

[263] McKesson, itself, recognizes the regulations outline those responsibilities. *See, e.g.,* Presentation, *McKesson's Controlled Substances Monitoring Program - Regulatory Affairs Training*, 25 (undated), MCKMDL00336532 at MCKMDL00336549 ["RA 2015 Training"]; *but see* N. Hartle Deposition, 17:20-23 and 18:1-6 (Aug. 1, 2018) (Establishing via metadata that the training deck discussed in the De Gutierrez-Mahoney deposition was created on December 31, 2015); *see infra* Report Section 3.2.5.

[264] *See* Memorandum from M. Mapes to J. Rannazzisi, *Internet Presentation with McKesson Corp. on September 1, 2005*, (Oct. 20, 2005), MCKMDL00496859; *see also* Memorandum from M. Mapes to J. Rannazzisi, *Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006*, (Jan. 23, 2006), MCKMDL00496876; *Summary of DEA-HDMA Mtg. on Suspicious Orders,* (Sept. 7, 2007), MCKMDL00574906; Letter from W. Ihlenfeld, II to G. Hobart, *Claims Against McKesson Corporation*, (Nov. 6, 2013), MCKMDL00409048; Letter from D. Cutteman, *et al*., to G. Hobart, *Registration Consequences for McKesson Corporation for Violations of the Controlled Substances Act*, (Nov. 4, 2014), MCKMDL00409453; Letter from W. Ihlenfeld, II to G. Hobart, *McKesson Matter – Ongoing Settlement Discussions*, (Mar. 20, 2014), MCKMDL00409174; Letter from J.F. Walsh to G. Hobart, *Possible Civil Action Against McKesson Corporation for Violations of the Controlled Substances Act*, (Aug. 13, 2014), MCKMDL00409224 at MCKMDL00409234

[265] *See* Letter from Wendy Goggin to John Gray (Oct. 17, 2008) (discussing HDMA's voluntary industry guidelines, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances.") WAGMDL00673706.

[266] *See, e.g.,* RA 2015 Training at 27.

9.4.3 McKesson's organizational design of the controlled substances program reflects a lack of support for controlled substances compliance efforts.

Until approximately four years ago, the controlled substances program within McKesson operated like a junior function within the company. Controlled substances compliance, including SOM, is the purview of U.S. Regulatory Affairs and Compliance (formerly known as U.S. Regulatory Affairs).[267]

It was not until mid-2015 while preparing for the eventual January 2017 settlement with the government that McKesson created a connection between those responsible for the controlled substances program and the "governing authority" of McKesson (e.g., the Board of Directors and Corporate Officers).[268] In the 2018 Teamsters Response report by McKesson's Board of Directors, the Board highlighted an example of what occurred in 2011 and 2012 because of that disconnect:

> Based on the Committee's investigation, it appears that neither the Company's Board nor Audit Committee were made aware at the time of the issues raised by the DEA in connection with the Ohio distribution center inspection or the new distribution center registration application.[269]

However, McKesson's remedy for this governance disconnect is only a partial solution. The new connection, as shown in Figure 3 below,[270] is an indirect ("dotted line") reporting relationship between the Senior Vice President, Regulatory Affairs and Compliance ("SVP, RA&C") and the Senior Vice President Compliance, Regulatory & Ethics (formerly, the Senior Vice President, Global Compliance & Ethics[271]), who in turn reports directly to the Chief Compliance Officer ("CCO"), a function that was established in 2006.[272]

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[267] *See* Presentation, *Controlled Substances Compliance Program* at P1.1743.9 (Nov. 1, 2013), MCKMDL00516748 ["Regional SOM Training"]. The slide states that regulatory is responsible for "overall management and administration of the CSMP program," as well as "oversight and audit of recordkeeping and reporting."

[268] *See* McKesson, *ISMC Controlled Substances Monitoring Program Operating Manual,* Version 1.1 at 6, § 3.1 (Jun. 1, 2015) (Version 1.0 was completed May 21, 2015), MCKMDL00337198 ["ISMC CSMP Manual 2015"]; *see also* RNA Controlled Substances Monitoring Program Operating Manual, Version 1.0, 5-6 (Apr. 17, 2018), MCKMDL00337622 ["RNA CSMP Manual 2018"]

[269] *See* McKesson Teamsters Response at 17.

[270] *See* McKesson*, ISMC Controlled Substances Monitoring Program Operating Manual*, Version 1.3 at 6, § 3.1, Figure 2 (Jan. 6, 2017), MCKMDL00395206 ["ISMC CSMP Manual 2017"].

[271] *See* ISMC CSMP Manual 2015 at 6, § 3.1, Figure 2.

[272] *See* Michael Johnsen, McKesson names new general counsel and chief compliance officer, DRUGSTORE NEWS (Jun. 23, 2014) at https://www.drugstorenews.com/news/mckesson-names-new-general-counsel-and-chief-compliance-officer/

Figure 3: Corporate Controlled Substance Governance Overview

Prior to the 2015 changes, U.S. Regulatory Affairs was a function located under the umbrella of U.S. Pharma Distributor Operations, which the Senior Vice President, Donald Walker led from 1997 to September 2015.[273] Distributor Operations in turn reported to the U.S. Pharma Chief Operating Officer, who reported to the President of U.S. Pharma, who in turn reported to the Group Vice President, who reported to McKesson's Chief Executive Officer.[274]

As a result, before the 2015 changes, U.S Regulatory Affairs was at least six levels down in the organization from the CEO and seven levels down from the Board of Directors depending on which function is considered the governing authority for FSGs purposes. In other words, U.S. Regulatory Affairs, and hence the controlled substances program, lacked direct Corporate senior management oversight or support.[275]

Furthermore, the changes in 2015 to create the "dotted line" relationship between the SVP RA&C and the SVP Compliance, Regulatory & Ethics, in my opinion, are form over substance. Regardless of the "dotted line" into the Corporate Compliance function, the SVP RA&C's primary allegiance is to the President, U.S. Pharma as a direct report of the President. Thus, the SVP RA&C from 2015 to the present has the same reporting

[273] *See* McKesson Corporation, Presentation to the USAO, Northern D. W. Va. and DEA, 7 (Mar. 12, 2014) (Walker identified as SVP, Distributor Operations), MCKMDL00409116 ["USAO Presentation 2014"], *see also* Donald Walker Profile at http://www.spoke.com/people/donald-walker-3e1429c09e597c10039327ad (last accessed Dec. 11, 2018) (Walker listed as SVP, Distribution Support in 2013).

[274] *See* Presentation, *U.S. Pharma Regulatory Affairs/Compliance, All-Hands Meeting 2016*, 9 (Oct. 24-26, 2016), MCKMDL00336634 ("RA All-Hands") and *see* ISMC CSMP Manual 2015 at 6, § 3.1, Figure 2.

[275] Although no formal governance link between the controlled substances compliance program and senior corporate management existed prior to 2015, there is evidence demonstrating McKesson Corporate was not totally unaware of what was happening. For example, in January 2006, Paul C. Julian, Executive Vice President, Group President for McKesson wrote a lengthy response to the DEA concerning discussion between McKesson and the DEA over the Lakeland Florida Distribution Center. *See* P.C. Julian 1/18/2006 letter to J.T. Rannazzisi.

relationship Mr. Walker had from 1997 to 2015. In short, nothing changed. McKesson could have accomplished significant change by simply making the SVP RA&C a direct report of the CCO with a dotted line to the President of U.S Pharma, giving the SOM staff a true measure of independence.

In a similar fashion, the creation of the Regulatory Operating Committee ("ROC") and the Controlled Substance Compliance Program National Governance Committee ("NGC") in 2014 appears to be more form than substance.[276] According to the 2015 ISMC CSMP Manual, the NCG's duties are to provide high-level oversight of the CSMP; propose and adopt changes to the program; assure that concerns and inquiries regarding the program are resolved in a timely manner; monitor drug diversion trends and the effectiveness of the program; review significant compliance risk areas; and ensure proper communication of significant compliance risks.[277] However, in the 2017 ISMC CSMP Manual, those duties were truncated to "high-level oversight of US Pharma's compliance with the CSMP, [and] US Pharma's compliance with the Controlled Substances Act and its implementing regulations."[278] With the exception of the Law Department and Internal Audit, NGC representatives are all senior U.S. Pharma employees.[279] In short, this is the same group of employees that was in charge of the SOM program from pre-2000 to 2014.

The ROC, on the other hand, "is responsible for program-wide decisions regarding the CSMP, implementation, and execution of CSMP enhancements, hiring and onboarding of the Regulatory Affairs team, and supporting the technology and work needs of the Regulatory Affairs team."[280] This committee consists of the SVP RA&C and his or her senior directors.[281]

Although the McKesson Board of Directors publicly touted how the company "enhanced its governance oversight of the CSMP"[282] by establishing the NGC and the ROC, neither of these two committees ironically has a formal place on the official organizational chart in the CSMP Manual.[283] Nor do they have a direct reporting responsibility to the "governing authority" of McKesson (e.g., the Board of Directors and Corporate Officers). This is unlike the CCO, who has a formal reporting relationship to the Board Audit Committee. Therefore, it is unclear whether these committees perform real oversight and force change or are simply informal group designations established to give the embattled U.S. Pharma management team more credibility and legitimacy.

McKesson's organizational design amounts to a serious deficiency as noted by the OIG, because "for a compliance program to be effective, it must have the support and commitment of senior management and the

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[276] *See* MCK Teamsters Response at 23.

[277] *See* ISMC CSMP Manual 2015 at 9; *see also* MCK Teamsters Response at 23.

[278] *See* ISMC CSMP Manual 2017 at 8.

[279] *See* ISMC CSMP Manual 2015 at 9; *see also* MCK Teamsters Response at 23.

[280] MCK Teamsters Response at 24; *see also* ISMC CSMP Manual 2015 at 7-8.

[281] *See* ISMC CSMP Manual 2015 at 7.

[282] MCK Teamsters Response at 23.

[283] *See* ISMC CSMP Manual 2017 at 6. The ROC and NDC also are not mentioned in McKesson's Annual Reports for FY2014 – FY 2016.

company's governing body,"[284] and the compliance function needs to be able "to effectuate change within the organization as necessary or appropriate and to exercise independent judgment."[285] The positioning of the controlled substances program so low in the corporate hierarchy and without any direct avenue to either McKesson's corporate officers or the Board of Directors is not a reasonable design to ensure effective compliance. In addition, it is another clear indication that McKesson neither supported nor is committed to ensuring that the SOM process and by extension the entire controlled substances program is optimized to be effective.

9.4.4 McKesson failed to resource the controlled substances program appropriately.

Before 2007 and the first DEA settlement, McKesson told the government that its regulatory affairs team consisted of 3 FTEs (2 SVPs and 1 Director of Regulatory Affairs).[286] From 2007 to 2012, McKesson expanded the team to 10 FTEs by adding another Director of Regulatory Affairs, and 6 Regional RA directors, one of whom was former DEA investigator.[287]

The years from 2012 to 2014 marked a period of headcount expansion for McKesson's controlled substances program. Between 2012 and the March 2014 presentation to the U.S. Attorney's Office, McKesson added 2 Senior Directors and 6 Directors plus 2 analysts and 10 regulatory affairs managers of which 5 were former DEA employees. According to McKesson, this brought the team's total headcount to 30 FTEs.[288]

As noted above, McKesson distributes controlled substances from numerous distribution centers ("DCs") nationwide. While the number of DCs fluctuated during the review period, in 2014 McKesson told the U.S. Attorney's Office and the DEA that the company had 28 customer facing distribution centers plus 2 redistribution hubs.[289] These centers serviced approximately 25,000 pharmacies and "processed 1.2 million order lines per night."[290] Analyzing those numbers specifically for controlled substances provides the additional insight that even after the headcount expansion that began in 2012 McKesson still only had one controlled substances Regulatory Affairs person for each distribution center and redistribution hub, who oversaw approximately 1,240 controlled substances orders per night involving on average 833 customers.[291]

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[284] *See* OIG Pharma Guidance at. 23731.

[285] *Id.* at 23739.

[286] *See* USAO Presentation 2014 at 7.

[287] *See* USAO Presentation 2014 at 8.

[288] *Id.* at 9.

[289] *See* USAO Presentation 2014 at 4.

[290] *Id.* Another significant headcount increase occurred once more when McKesson prepared to conclude its second settlement with the DEA that was consummated in January 2017. *See* ISMC CSMP Manual 2017 at 6, § 3.1, Figure 3.

[291] Using the data from Appendix C, Figure 1, the formula for number of nightly controlled substances orders was [1.2 million (number of daily line times) x .031 (% of controlled substances sales (using lowest figure))] /30 (number of distribution centers) = 1,240. Assuming every McKesson customer sells controlled substances in 2014 (25,000 customers)/30 FTEs) = 833.33 customers per staff member.

Comparing this data with the number of full-time equivalents ("FTEs") in the controlled substances program reveals two important insights. First, the increase from 3 FTEs to more than 40 over 10 years appears to be a tacit admission by McKesson that the company knew its SOM program was under-resourced.[292] Second, even with the headcount additions provided to the program by March 2014, McKesson's controlled substances program remained significantly under-resourced when factoring in the DEA's basic expectations to "know your customer" and report suspicious orders.

Substantial compliance headcount increases are a common response to settlement agreements as a company seeks to integrate the additional burden of administering the settlement provisions into its customary, pre-settlement workload. For example, as a result of their Corporate Integrity Agreements, both Pfizer and GSK significantly expanded their compliance teams. Compliance headcount increases also are commonplace as a normal part of organizational growth. During the review period, McKesson experienced significant revenue growth.[293] However, these headcount increases due to organic growth are usually more incremental than exponential. In my experience, this dramatic an increase in compliance headcount is a clear indication that McKesson recognized its controlled substances program was significantly under-resourced.

As McKesson's own internal policies acknowledge, the DEA expectation of "know your customer" involves "understanding the customer's business, *why* they purchase as well as how much they purchase," and factors that should be considered include "type of business, internet activities, type and quantity of products purchased."[294] It also requires that when "red flags" or potential indicators of diversion are identified during the ordering process, that each order is reviewed to determine whether the order should proceed or not.[295] Working with McKesson's data disclosed to the U.S. Attorney's Office and others, at the 2014 staffing level of 30 FTEs for SOM and assuming every team member is doing some suspicious order reviews, each team member had to review approximately 18 new suspicious orders per day.[296] By 2017, that number drops to approximately nine (9) per day per staff member, which is still a significant workload.[297]

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[292] *See* ISMC CSMP Manual 2017 at 6, § 3.1, Figure 3.

[293] *See* MacroTrends, *McKesson Revenue 2006 to 2018* at https://www.macrotrends.net/stocks/charts/MCK/mckesson/revenue (last accessed Dec. 12, 2018) (Showing McKesson revenue more than doubled during the period).

[294] *See* McKesson Operations Manual for Pharma Distribution, *Lifestyle Drug Monitoring Program*, 1 (May 16, 2007) (emphasis in the original) (This program was only in effect from May 2007 until May 2008 when it was replaced by the CSMP), MCKMDL00330211 ["LDMP Manual"]; CSMP Manual 2011 at, 19 ("McKesson's responsibility is to "Know our Customer."); *see also* Boggs Presentation at 39 (Sept. 30, 2013).

[295] *See* McKesson CSMP "Red Flags," 1 (May 2015), MCKMDL00335740; *see also* CSMP Manual 2011, § 6.1; *see also Masters Pharmaceutical, Inc. v. DEA*, No. 15-1335, Op. 5 (D.C. Cir. 2017) (" Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." citing DEA, *Southwood Pharmaceuticals., Inc – Revocation of Registration.,* 72 Fed. Reg. 36487, 36500 (Jul. 3, 2007)); *See* James Arnold presentation, *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conference, 41 (Jun. 2013) available at https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/. .

[296] Using the data in Appendix C, Figure 1, the formula used was [3-year average of suspicious orders/number of days per year]/number of FTEs = result. Therefore, ([(230,000 + 220,000 + 145,000)/3]/365)/30 = 18.1.

[297] Again, from Appendix C, Figure 1 data, [(145,000 number of SOs in 2017)/365 days per year]/44 FTEs = 9.02.

On top of reviewing suspicious orders, the controlled substances staff members are each responsible for "knowing" approximately 833 customers, including performing onboarding, and actively monitoring the information that could affect ordering patterns (e.g., region served, county population, sale representative visit information, etc.).[298] By 2017 that number had climbed to 909 customers per staff member.[299]

Finally, the controlled substances program staff members also have other compliance "back office" work such as training, writing reports, updating policies and procedures, etc. to address. The bottom line is that even with McKesson's headcount expansions post-2014, the compliance workload per person is not sustainable to achieve effective compliance.

9.5 Program Core - Requirements, Education, Detection & Corrections

Written standards, employee education, detecting and correcting breaches of the company's written standards and the law are at the core of an effective compliance program. However, in each of these areas, the data I reviewed demonstrates that McKesson came up short such that McKesson's controlled substances program overall was ineffective to detect and prevent instances of controlled substances diversion during the review period. Furthermore, McKesson knew or should have known that its program was inadequate.

9.5.1 McKesson's Code of Conduct does not meet generally accepted compliance standards

The earliest version of the McKesson Corporation Code of Business Conduct and Code of Ethics ("Code") reviewed dates to February 2009.[300] However, the Code's copyright footer notes 2005, 2006 and 2009 suggesting that McKesson's first Code dates to 2005 or 2006, approximately the same time that McKesson named its first Chief Compliance Officer.[301] The Code states that it "applies to all McKesson personnel, which includes every McKesson officer, director, employee, and agent."[302]

The Code also contains a section entitled "Interacting With Government" that is focused primarily on federal health care fraud and abuse laws.[303] While the Code covers many of nuances such as the Federal False Claims Act, the Foreign Corrupt Practices Act and lobbying, nowhere is controlled substances compliance highlighted. Thus, controlled substances compliance is at best covered under the general catch-all "we should … [c]onduct all work and business affairs lawfully and with integrity.[304]

[298] This analysis assumes that every McKesson customer sells controlled substances. Therefore, using 2014 data from Appendix C, Figure 1, 25,000 customers)/30 FTEs= 833.33 customers per staff member.

[299] Using 2017 data from Appendix C, Figure 1, 40,000/44 = 909.09 customers per staff member.

[300] *See* McKesson Corp., *McKesson Corporation Code of Business Conduct and Code of Ethics Code* (Feb. 2009), MCKMDL00375003 ["2009 Code"]

[301] *Id.*

[302] *Id.* at 1.

[303] *Id.* at 20-26.

[304] *Id.* at 1-2.

Since 2009, the McKesson Code has been amended several times, with the most recent changes being made in August 2018.[305] However, while the Code of Conduct continues to specifically address certain standard risk areas found in most company codes, McKesson's 2018 Code still does not have a corresponding specific section addressing controlled substances compliance. This is despite McKesson entering into settlement agreements with the DEA on multiple occasions and paying substantial fines.[306] The 2018 version also does not contain an "Interacting With Government" section.

The lack of any mention of complying with the controlled substances laws and regulations is at odds with McKesson's representations in the 2017 Compliance Addendum that:

> McKesson understands that policies and procedures, such as a Code of Conduct, are central components to an effective controlled substance monitoring program, and further, that maintenance and oversight of policies to address DEA requirements create a culture of compliance in support of those requirements.[307]

Generally, a company's code of conduct addresses the compliance risk areas that are most important to the company, which is the point the Compliance Addendum is making. Therefore, by not including a section on controlled substances in its Code of Conduct, McKesson's does not meet generally accepted compliance standards and is not aligned with the Compliance Addendum's representations about McKesson's understanding of the Code's importance.

9.5.2 McKesson's standards outlining its controlled substances program were poorly organized and drafted undermining the primary purpose for creating standard policies and procedures.

Throughout the review period, McKesson's written standards outlining its controlled substances program were poorly organized and drafted which undermined the primary purpose of standard policies and procedures – achieving consistent compliance. Length, poorly defined objectives and ambiguous definitions all contribute to the program manuals being difficult to traverse and determine how the SOM process operates.

A. Drug Operations Manual, Section 55

The earliest manifestation of McKesson's controlled substances program that I reviewed is dated from 1997.[308] Informally known as Section 55, this was the program manual in use from at least 1997 to May 2007. The

[305] *See* McKesson Website, https://www mckesson.com/investors/corporate-governance/code-of-conduct/, (last accessed November 29, 2018) (Amendments occurred in 2013, 2016 and 2018). The 2018 amendments occurred because McKesson "updated its Code of Conduct to reflect rebranding of its business operations in the European Economic Area and European Union under the consolidated name McKesson Europe, including translated versions for each of the different sub-brands and countries in which the company operates."

[306] *See* McKesson Code of Conduct, Table of Contents at ii, available at https://www.mckesson.com/documents/investors/mckesson-code-of-conduct/ (last accessed Dec. 5, 2018). The Code does contain the standard compliance statement that "[w]e comply with applicable laws everywhere we do business around the world." *Id.* at 1.

[307] *See* MCK Compliance Addendum at 2, section § II.A.

[308] *See* Memorandum from D. White to Distribution, *Drug Operations Manual Section 55-DEA Compliance* (Jan. 15, 1997) (MCKMDL00651873).

controlled substances chapter is a 137-page, detailed recitation of the DEA regulations, and a description of how to fill out various required forms, physical security requirements, which also includes a section on suspicious orders.[309] Section 55 is missing standard procedural sections such as responsibilities and definitions. The chapter also does not contain step-by-step instructions to tell an employee how to perform suspicious order monitoring. Therefore, as a basic standard operating procedure, Section 55 is deficient.

Section 55 also does not meet the basic DEA requirements for a SOM Program. In the suspicious order section (IV), Section 55 outlines five different reports concerning a customer's purchases (Controlled Substances Sales Report, Controlled Substances Customer Purchase Report, Daily Controlled Substance Suspicious Order Warning Report, Monthly Controlled Substance Suspicious Purchases Report and the Monthly ARCOS Customer Recap Variance).[310] Despite the fact that the section quotes the DEA requirements around suspicious orders, and lists these system generated reports, there was no apparent requirement for McKesson employees, Distribution Center Managers, Operations Managers or Warehouse Staff (DCM/OM/WS) to take any action other than review the Suspicious Order Warning Reports, sign to acknowledge the review had been done nightly, fax a copy to the local DEA Office and file it in the appropriate file folder.[311] Thus, there was no documented obligation for the McKesson staff members to place the orders on hold or investigate the reason for the customer appearing on the report.

The output from these reports, known as DU-45 reports, was also rudimentary. Customers appeared on the DU-45 report when sales of controlled substances, including opioids, to that customer exceeded three times of that customer's 12-month purchase average for that base code.[312]

These standards are clearly at odds with the DEA requirements that distributors must know their customers and therefore must investigate the circumstances surrounding their orders to determine if any should be submitted to the DEA as suspicious and/or whether the order appears to be indicative of diversion and stopped.[313] As outlined by Dave Gustin, "the previous reports [under Section 55] were not the exclusive and proper response to this regulation. We have an obligation to report 'suspicious orders.' With no clear definition of what constitutes a suspicious order, we must rely on our own judgment as to what that is. If we report anything, we believe to be truly suspicious we will be meeting the spirit and letter of the regulation. Simply reporting larger than usual orders does not when there are so many plausible and routine reasons for orders to be 'larger than normal.'"[314]

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[309] *See generally* McKesson, *Drug Operations Manual Section 55 DEA Compliance* (Jul. 2000), MCKMDL00346554) ["Section 55"].

[310] *See* Section 55 at 28-30, § IV.A.2.a-e.

[311] *See* Section 55 at 31-32, § IV.B.2 (Section IV.B.2.d also notes that "[w]e are required by federal law to report suspicious orders upon discovery.").

[312] *See* McKesson, *Drug Operations Manual Section 55 DEA Compliance*, MCKMDL00651919-20 (Jan. 27, 1997), MCKMDL00651873; Gary Hilliard Deposition, 163:21-169:7 (Jan. 10, 2019).

[313] *See* Discussion *infra* at Section 5.3.

[314] *See* Email from D. Gustin to T. Williams, *et al.*, RE: Variance and Suspicious Reports (Feb. 4, 2011), MCKMDL00510747; *see also* McKesson, DU45R05B8165 Monthly Controlled Substance Rpt., (Apr. 3, 2007) (This example report is 647 pages), MCKMDL00660789

B. Lifestyle Drug Monitoring Program

Although extremely short-lived (May 2007 to May 2008), McKesson's next documented program was the Lifestyle Drug Monitoring Program or "LDMP." The program was created as a result of the DEA's concerns over internet pharmacy sales of controlled substances.[315] Although considered by McKesson as a controlled substances compliance program, the LDMP program does not constitute a complete controlled substance compliance program as it was limited to just four drug products (oxycodone, hydrocodone, alprazolam, and phentermine).[316] However, during the period the LDMP existed, McKesson distributed other controlled substances such as hydromorphone, methadone, and morphine,[317] but McKesson did not monitor those others drugs. Instead, McKesson only monitored what the DEA "told them to" and expressly noted that "[t]he list of substances monitored by McKesson will only be adjusted when and if the DEA focus list is modified."[318] Thus, McKesson committed to only doing the bare minimum, but from a regulatory perspective that "bare minimum" was deficient from the outset.

Although the LDMP manual is closer to a conventional SOP format, it still lacks critical components such as definitions, an outline of the specific responsibilities for key personnel (responsibilities section), effective date and revision history.[319] As a result, it is impossible for an employee to know (other than taking it at face value) whether the document was properly approved, or when it became effective. These deficiencies create a large compliance loophole. Nor is it clear whether general employees at McKesson's distribution centers have any responsibilities under the LDMP or whether that is reserved for employees at the level of DCM and above.

C. Controlled Substances Monitoring Program

Replacing the LDMP, the Controlled Substances Monitoring Program or "CSMP" came on-line in 2008, and although modified on several occasions, it remains in use today. A review of the 2011 Manual, which is substantially similar to the 2008 version for this discussion, reveals that McKesson added a revision history section to the manual.[320] As with the previous program manuals, the 2011 CSMP still lacks a formal responsibilities section, which makes it difficult for various functions and employees in general to determine their roles.

With the 2015 introduction of two CSMP manuals, one for the Independent Small Medium Chains ("ISMC")[321] and ultimately one for Retail National Accounts ("RNA") customers,[322] McKesson finally adopted the standard

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[315] *See* Walker Internet Presentation at 3-6. *see also See*, *e.g.,* Sandy Campbell, *Lifestyle Drug Program*, McKesson U.S. Pharma DEA Licensure Audit, 1 (last revised Jul. 27, 2007), MCKMDL00591949-00591953 ["LDMP Narrative"]; Letter from J. Gilbert to L. Barber (Apr. 25, 2007)(Mr. Gilbert from Hyman, Phelps & McNamara was McKesson's outside counsel and Mr. Barber was Associate Chief Counsel in the Office of Chief Counsel, Diversion and Regulatory Litigation Section, DEA), MCKMDL00330924 (Also stamped MCK-HOI-002-0000001).

[316] LDMP Narrative at 2.

[317] *See* McKesson Regional Statistical Norms, 2 (Feb. 24, 2014), MCKMDL00430387 at MCKMDL00430388.

[318] *See* LDMP Narrative at 2.

[319] *See* LDMP Manual.

[320] *See* CSMP Manual 2011, 24-26.

[321] *See* ISMC CSMP Manual 2015.

policy and procedure elements, but at the same time it increased the program's complexity by creating two separate CSMP manuals. These dual manuals necessitate the use of additional resources to ensure the CSMP provisions common between them are always aligned, and potentially raising questions (and compliance breakdowns) for employees as to which manual governs their day-to-day activities, as distribution centers service both ISMC and RNA customers. This added complexity was something that McKesson recognized, but nevertheless persisted in keeping both manuals.[323]

9.5.3 McKesson's *ad hoc* approach to controlled substances education for its employees did not and still does meet generally accepted compliance standards.

Although an effective compliance program is expected to have a formal and robust training and education program surrounding the requirements for a controlled substances distributor and how McKesson meets those requirements, there is scant evidence that McKesson had any kind of a systematic approach to controlled substances training prior to 2015. In fact, two LDMP audits conducted in 2007 noted that "[t]he greatest barrier to success of the LDMP is the lack of understanding of the DEA expectations."[324] This was also aptly illustrated by Blaine Snider in his deposition when he testified that although he followed the Code of Federal Regulations pertaining to the distribution of controlled substances and SOM, he did not know the phrase "legitimate medical purpose" nor had he heard of the Controlled Substances Act or the September 2006 DEA letter to all registrants.[325]

Section 55, the LDMP Manual and prior iterations of the CSMP Manual all fail to reference a training program.[326] The 2013 CSMP Manual makes a brief reference to that the fact that "[i]n addition to other continuing education efforts regarding regulatory compliance, the DC's and sales groups will receive an annual CSMP SOP overview and continuing education. The intent of this continuing education is to refresh/remind McKesson personnel of their CSMP responsibilities and instill consistency on CSMP processes."[327]

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[322] *See* RNA CSMP Manual 2018. While started in 2015 when the separation occurred (*see* Email from A. Palmer to M. Oriente, Family Code Request Examples, (Aug. 20, 2015), MCKMDL00628803.), the process was not completed until April 2018 more than 2-1/2 years later during which time the RNA group operated under SOPs that technically did not apply to them.

[323] *See* Email from L. Brenner to N. Hartle, FW: RNA Operating Manual – Next Steps, (Apr. 11, 2018) ("The key thing we have to keep in mind is that to the extent this Manual is different from the ISMC Manual, the DEA will likely ask why, and we have to be prepared with defensible answers. So, one of the helpful things to discuss or flesh out in the RNA Ops Manual is why there is for example more flexibility in places, or less detail, or less mandatory specific documentation or diligence."), MCKMDL00570154.

[324] *See* Gwen Allen, *Lifestyle Drug Program, McKesson U.S. Pharma – DEA Licensure Audit, So Cal DC*, 4 (Aug. 23, 2007), MCKMDL00591858; *see also* Sandy Campbell, *Lifestyle Drug Program, McKesson U.S. Pharma – DEA Licensure Audit, Washington Court House*, 3 (Aug. 10, 2007), MCKMDL00591862.

[325] *See* Blaine Snider Deposition, 23:4-13. 24:4-15, 34:4-6 and 74:1-6 (Nov. 8, 2018). Snider was Director of Operations for the New Castle, PA distribution center from 2000 to the present. *Id.* at 19:7-13.

[326] *See generally* Section 55; LDMP Manual; CSMP Manual 2011.

[327] *See* McKesson Operations Manual, *Controlled Substances Monitoring Program*, 25, § 8 (Mar. 21, 2013), MCKMDL00002509 ["CSMP Manual 2013"].

In May 2013, McKesson employees were notified by Pharma Operations that McKesson shortly thereafter was going require managers to "partake in a yearly continuing education and attestation of the CSMP Standard Operating Procedure."[328] Sharon Longwell, Vice President of National Account Support Services, responded: "I have copied the [CSMP] manual so my team can see it because I don't think we have ever seen this manual before."[329] This exchange between Mrs. Jonas and Ms. Longwell indicates that (a) routine controlled substances training did not occur prior to 2013, and (b) that McKesson failed to ensure that the CSMP manual was distributed to all employees needing access to it.

Also, I have seen no examples of standard on-boarding training materials before 2015. Furthermore, when the Regulatory Affairs group met on March 5-6, 2008 to discuss the roll-out of the original CSMP program, the meeting notes did not reflect any discussion about training or even list it as an item to be covered.[330]

The 2015 ISMC CSMP Manual appears to be the first instance of McKesson formally documenting detailed SOM training requirements.[331] It references three types of training: regulatory affairs new hire training, sales, and operations training, and customer education and awareness sessions. Although this represents an improvement from the previous undocumented, *ad hoc*, approach, the standard controlled substances training was still significantly flawed, which has carried through to the current program.[332]

First, the training for regulatory affairs personnel is for new hires only.[333] The program contains no mention of refresher training programs or training on future program changes.

Second, the RA training program contains no method for conducting objective assessments, rather it is up to "the manager of the new Regulatory Affairs personnel [to] provide training and oversight until he or she determines that the new hire has been adequately trained on such new hire's CSMP responsibilities."[334] This is a nebulous standard that lacks sufficient rigor and is widely variable.

Third, with the exception of sales and operations training, no log associated with either RA new hire training or customer education was observed.[335] Further, the manual does not specify what the log captures, which it

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[328] *See* Email from T. Jonas to S. Longwell, *et al.*, Required Controlled Substance Training (May 1, 2013) ("p.s. Managers as identified in PeopleSoft are CC'd in this email."), MCKMDL00521761 at MCKMDL00521763.

[329] *See* Email from S. Longwell to T. Jonas, RE: Required Controlled Substance Training (May 2, 2013), MCKMDL00521761 at MCKMDL00521762.

[330] *See* Email M. Oriente to D. Walker, *et. al*, Regulatory Meeting 3/5 & 3/6, Attachment (Mar. 7, 2008), MCKMDL00545048; *cf.* Email from C. Scofield to T. Jones, *et. al,* CSMP Sales Presentation (Mar. 7, 2008), MCKMDL00267635 (Training was not mentioned in the presentation either) ["CSMP Sales Presentation 2008"]; RA 2015 Training at 48.

[331] *See* ISMC CSMP Manual 2015 at 46, § 9.

[332] *See* ISMC CSMP Manual 2017 at 43 § 9; *cf.* ISMC CSMP Manual 2015 at 46, § 9. Apart from some minor changes, section 9 remains largely unchanged between the 2015 and 2017 versions.

[333] *See* ISMC CSMP Manual 2015 at 46, § 9.1.

[334] *See* ISMC CSMP Manual 2015 46, § 9.1.

[335] *See* ISMC CSMP Manual 2015 46, § 9.2.

should.[336] Therefore, it is unclear whether attendance at training and educations sessions is captured and recorded.

General employee communications about controlled substances requirements and McKesson's anti-diversion program appear to have even less formality and structure than its training program. In fact, based on the documents reviewed, it seems that U.S. Pharma senior management only communicated with employees about the controlled substances program when absolutely necessary, such as during settlement discussions with the DEA.[337]

9.5.4 As early as 2005, McKesson knew its SOM program was not in compliance with DEA requirements.

Despite the obligations around controlled substance diversion controls and reporting suspicious orders dating back to the 1970s, it seems that McKesson did not use thresholds as a control mechanism to limit suspicious orders until the start of the LDMP in May 2007.[338] According to Section 55 of the Drug Operations Manual, the predecessor to the LDMP, McKesson performed very limited monitoring. This lack of even a rudimentary controlled substances compliance program led to predictable failures, which the DEA ultimately highlighted to the company in 2005 and 2006.

In September 2005, the DEA met with McKesson representatives, during which the Agency highlighted two specific McKesson pharmacy customers with suspicious ordering patterns for hydrocodone.[339] As part of the discussions, the DEA also reminded McKesson that it was required to: (a) report suspicious orders to DEA when discovered, (b) not rely on the DEA to determine if a suspicious order is legitimate, and (c) stop selling if they detected diversion.[340] McKesson acknowledged in the meeting that it understood those obligations under the CSA.[341]

At a later meeting between McKesson and the DEA in January 2006, the DEA highlighted six more McKesson pharmacy customers in Florida which were purchasing large quantities of hydrocodone.[342] According to the DEA in an 11-day period in October 2005, these pharmacies received between 158,400 dosage units (Bi-Wise Pharmacy) to 520,200 dosage units (Avee Pharmacy) of hydrocodone.[343] According to the DEA minutes of the meeting, "McKesson Corp., by its own admission, was unable to provide a plausible explanation for the sales of

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[336] *See* ISMC CSMP Manual 2015 46, § 9.2.

[337] *See, e.g.,* CSMP Sales Presentation 2008 (Program update because of 2008 DEA settlement); RA 2015 Training at 48 (Referencing April 30, 2015 All Hands Call about the agreement in principle with DEA and DOJ).

[338] *See infra* Report Section 9.5.2 (Discussing Section 55's lack of obligation to act on suspicious order reports except to do a cursory review and provide to the DEA Field Office.).

[339] *See* Memorandum from M. Mapes memorandum 10/20/2005 to J. Rannazzisi at 1.

[340] *See* Presentation, *Internet Pharmacy Data,* Meeting with McKesson Corporation, DEA Headquarters, 7, 8, 13 (Sept. 1, 2005).

[341] *Id.* at 1.

[342] *See* M. Mapes 1/23/2006 memorandum to J. Rannazzisi at 2.

[343] *See id.*

over two million dosage units in a 21-day [sic.] period, to pharmacies previously identified by DEA to McKesson Corp.[344] At the meeting, Gary Hillard, Director of Regulatory Affairs for McKesson, also disclosed to the DEA that McKesson's monitoring efforts for hydrocodone were deficient because they only tracked branded products and did not include generics.[345]

Individually, these sales in October 2005 ranged from 31.6 to more than 100 times greater than the 5,000-dosage unit monthly threshold level average that the DEA expected; all in approximately one-third of a month. Clearly those purchases and purchasers were "suspicious" and warranted further investigation whether through a simple application of common sense or the DEA's recitation of circumstances that might indicate diversion.[346] Furthermore, sales of that magnitude also should not have continued until cleared by thorough company investigations.[347] Therefore, by the time McKesson rolled out the LDMP in 2007, the company already had customers engaging in diversionary behavior that the DEA repeatedly noted and brought to the company's attention, but which McKesson failed to address properly.

9.5.5 McKesson's LDMP continued the company's non-compliance due to poor program design and implementation.

While the LDMP can fairly be characterized as a rudimentary attempt at a controlled substances compliance program, the LDMP design and implementation flaws were such that they predictably resulted in customers exceeding the 8,000-dosage unit monthly thresholds. As a result, the LDMP cannot be legitimately viewed as providing "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[348]

A. Establishing the Thresholds

The LDMP Manual describes the monitoring program as follows:

> [The] Daily Dosage Summary and Dosage Limit Tracking Detail have been developed to allow McKesson to monitor customer purchases of controlled substances by the net number of dosage units sold based on the DEA's Controlled Substance Generic Base Code ID. McKesson will investigate customer activity when sales of a given generic base ingredient exceed a predefined dosage unit threshold within a calendar month. … The same dosage threshold will be used for all classes of customers.[349]

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[344] *See id.*

[345] *See id.*

[346] *See* DEA 9/27/2006 Letter at 2.

[347] *See, e.g.,* DEA 6/12/2012 Letter at 2.

[348] *See* 21 U.S.C. § 823 (b)(1).

[349] *See* LDMP Manual at 1.

The threshold level was set at a generic level of 8,000 by the Regulatory Department.[350] While having a set threshold is an improvement over the previous version of the SOM program, McKesson does not appear to have either a logical or statistical basis for setting the level at 8,000 dosage units per month. The absence of a sound basis for the threshold level manifested itself in two ways.

First, the threshold level applied to all classes of customers from independent, small and medium pharmacies to large national pharmacy chains. Having a single, uniform threshold did not comport with the DEA's requirements to "know your customer" and the need to individualize diversion detection. Thus, it appears that McKesson designed the LDMP to "check the box" that it had a controlled substances compliance program, rather than to develop a truly effective process.

Second, McKesson was aware that the DEA believed that the threshold level triggering further investigation was 5,000 dosage units per month on average.[351] McKesson, however, set its threshold level to trigger further investigation a full 37.5% higher. Although there is no definitive documentation outlining why McKesson set the threshold so much higher than DEA expectations, Paul Julian's letter to the DEA in January 2006 provides a possible explanation. In his letter, Mr. Julian referenced the DEA's 5,000 dosage unit expectation and went on to note that McKesson had more than 85 pharmacy customers ordering more than 5,000 dosage units of hydrocodone per month from the Lakeland, Florida distribution center alone.[352] Therefore, one possible explanation is that McKesson set the threshold level at 8,000 dosage units per month to avoid the need to make potentially disruptive adjustments to the numerous customers that were ordering more than 5,000 dosage units per month of hydrocodone.

B. The Daily Dosage Summary Report

Everything in the LDMP program keyed off the Daily Dosage Summary report. However, as Sandy Campbell's narrative documenting the LDMP in July 2007 revealed, the Daily Dosage Summary report was flawed in at least two crucial respects. First, she noted that "it is possible not all of the products containing one of the generic ingredients are included."[353] This failure to monitor generic products was the same failure Gary Hillard told the DEA about during their January 3, 2006 meeting more than 18 months earlier.[354] It remained uncorrected in the latest iteration of McKesson's SOM system although according to Ms. Campbell's narrative it would be corrected at some unspecified future date.[355] The second flaw she noted was that the Daily Dosage Summary report was organized by distribution center ("DC"), and therefore a customer could both exceed the monthly 8,000 dosage unit threshold and avoid detection by spreading its purchases across multiple distribution

[350] *See* LDMP Manual at 2, § 1.1; LDMP Narrative at 2.

[351] *See* P.C. Julian 1/18/2006 letter to J.T. Rannazzisi, at 3-4 ("DEA has stated that monthly sales of over 5,000 dosage units of hydrocodone should be used as a flag to whether the pharmacy is dispensing legitimate prescriptions."); *see also* Walker Internet Presentation at 4

[352] *See* P.C. Julian 1/18/2006 letter to J.T. Rannazzisi at 4.

[353] LDMP Narrative at 3.

[354] *See* M. Mapes 1/23/2006 memorandum o J. Rannazzisi at 2.

[355] *See* LDMP Narrative at 3.

centers.[356] Therefore, the base report the Distribution Center Managers ("DCMs") relied upon to identify potentially suspicious orders was corrupted rendering the program ineffective from the outset.

C. LDMP Escalation Process

The LDMP program provided for a 3-tier escalation process that was triggered once a customer exceeded the threshold of 8,000 dosage units in a month.[357] Once triggered, the DCM was instructed by the LDMP manual to evaluate the customer's previous three month's purchases, and examine whether:

- Previous sales were validated and approved.
- Sales have not increased more than 25% from any previous month.
- Sales are not increasingly steadily.
- Sales are consistent with customer type.
- Sales are consistent with any previous Sales or Customer communication.[358]

Once complete, "if the evaluation indicates that the customer's purchases are reasonable and that no further investigation is required," the DCM could approve the shipment.[359] Only if the evaluation was inconclusive was Level 2 invoked, and Distributor Operations or Regulatory Affair was notified, as well as a site visit and a customer interview initiated.[360] In addition to the substantial amount of work required for each excursion above the threshold, the LDMP program contained no objective criteria for determining when purchases were reasonable or what constituted an inconclusive evaluation.

The escalation process also did not provide for a hard cut-off to customers being reviewed to prevent potential diversionary orders from being filled.[361] This is in direct contravention to DEA's expectation and explicit directions as outlined in the DEA's September 27, 2006 letter written before the start of the LDMP program that;

> a distributor has a statutory responsibility to exercise due diligence to **avoid filling suspicious orders that might be diverted** into other than legitimate medical, scientific, and industrial channels. . . the distributor should exercise due care in **confirming the legitimacy of all orders prior to filling**.[362]

By not providing hard cut-offs, McKesson created a "paper program" (e.g., one that looks good on paper, but in practice does little to achieve compliance) and allowed potential diversionary situations to continue unabated. For example, there was the case of Franklin Pharmacy (also discussed separately above). In November 2007,

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[356] *Id.*

[357] *See* LDMP Manual at 2, § 1.1

[358] *Id.*

[359] *Id.* at 3, §§ 1.2 and 1.4.

[360] *Id.* at 3-4, §§ 2.1 to 2.4.

[361] *See* W. De Gutierrez-Mahoney Deposition, 584:11-17 (Admitting that there was no hard blocking of orders submitted by customers undergoing LDMP review).

[362] DEA 9/27/2006 Letter at 2 (emphasis added.)

Franklin Pharmacy triggered a review when it exceeded the threshold by 1,733 dosage units on November 13th.[363] However, by month's end, Franklin Pharmacy had received 22,250 dosage units or almost three times the threshold limit, and the Level 2 review was still not completed by December 10th.[364] But, Franklin Pharmacy was not alone. That same November 2007 report included Mace's Pharmacy (28,100), MedFast New Castle (33,100) and Town & Country (28,932) all of which were detected soon after crossing the threshold, yet all continued to place and receive orders through the end of the month.[365]

In addition, as these examples illustrate, McKesson misrepresented how the program worked to the DEA. In April 2007, McKesson's outside counsel wrote to the DEA that the company would not ship more than 8,000 dosage units per month to customers until due diligence was completed and would terminate and notify DEA about any account "where it cannot adequately justify the request to purchase in excess of 8,000 dosage forms per month."[366]

9.5.6 Under the CSMP, threshold setting combined with other techniques resulted in a SOM program that continued to be non-compliant with the basic DEA requirements for controlled substances, as well as the terms of the company's 2008 settlement agreement.

McKesson replaced the LDMP program with the new Controlled Substance Monitoring Program or "CSMP" in 2008. The CSMP utilized a threshold system and for the first time created a mechanism by which orders could be blocked once that threshold was met in a given month. However, as the DEA repeatedly noted, the CSMP program consistently failed to highlight more than a few suspicious orders despite increasing levels of controlled substances purchases by McKesson customers.[367] The DEA also expressed concern that McKesson in utilizing the CSMP failed to adhere to its obligation to "maintain a compliance program designed to detect and prevent diversion" as agreed in the 2008 settlement.[368]

Based on my review, improper threshold setting as well as the use of various other techniques such as buffers, threshold disclosure, and threshold change requests ("TCRs") combined to result in a gross under-reporting of suspicious orders and rendered the CSMP as ineffective as the LDMP as a tool to prevent diversion.

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[363] *See* Email form Alexandra Feigel to Diane Martin, RE: November LDMP (Dec. 10, 2017) (Responding to D. Martin's email providing the November LDMP data), MCKMDL00540033.

[364] *Id.*

[365] *Id.*

[366] Letter from J. Gilbert to L. Barber at 3 (Apr. 25, 2007) (Mr. Gilbert from Hyman, Phelps & McNamara was McKesson's outside counsel and Mr. Barber was Associate Chief Counsel in the Office of Chief Counsel, Diversion and Regulatory Litigation Section, DEA), MCKMDL00330924 (Also stamped MCK-HOI-002-0000001).

[367] *See* Letter from D. Cutteman, *et al*., to G. Hobart; Letter from W. Ihlenfeld, II 3/20/2014 letter to G. Hobart; J.F. Walsh 8/13/2014 letter to G. Hobart.

[368] *See* 2008 MOA at 3, § II.1(a).

A. Establishing Thresholds

Building off the LDMP, the 2008 CSMP program thresholds were the result of an "[a]nalysis [that] was conducted on every McKesson customer."[369] As a result, "[t]hresholds with an additional margin were established based upon a review of the customers' purchases over a twelve-month limit."[370] With the 2008 CSMP, McKesson also initiated a "Family Threshold Limit" for brand-new customers that were based on a "Six Sigma analysis [that] helped to identify appropriate threshold amounts for every controlled substance and for every family type. Out of that information, a matrix of family codes and threshold amounts were developed."[371] This same methodology was reflected in the 2013 CSMP Manual, which was utilized after the 2008 DEA settlement.[372]

Both the 2011 and 2013 CSMP Manuals are extremely unclear as to exactly how McKesson derived the threshold numbers, especially as applied to existing customers. For example, the CSMP Manual did not state whether the base threshold was an average of a customer's purchases over 12 months, or the single highest month. However, both the government and Mr. de Gutierrez-Mahoney confirmed it was the single highest month over the year.[373] By picking the single highest month from the previous 12 months to set the base threshold number, McKesson was "cherry-picking" the data while attempting to maintain that the company used a sound methodology. This process also undermined the entire purpose of the SOM program, which was meant to identify and report suspicious orders by creating an artificially high threshold limit that would likely never be met by the customer..

The Manuals also did not define what the additional margin (i.e., buffer) was or its amount, although both the government and Mr. de Gutierrez-Mahoney confirmed it was an additional 10%. While the 2015 CSMP Manual increased the level of detail surrounding the setting of thresholds, the end results were the same.

According to the 2015 CSMP Manual, McKesson developed a set of default thresholds for new customers, based on McKesson's [redacted].[374] For example, the default monthly threshold for hydrocodone was set at [redacted], and oxycodone was set at [redacted].[375] The majority of the other product defaults on the list range from [redacted] units.[376] However, because the defaults for both hydrocodone and oxycodone were based on the [redacted]chases, and many McKesson customers were already getting large amounts of hydrocodone and oxycodone,[377] the [redacted] approach resulted in

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[369] *See* CSMP Manual 2011 at 2, § 1.1.

[370] *Id.*

[371] *See* CSMP Manual 2011 at 3, § 1.1.2

[372] *See* CSMP Manual 2013 at 2-3, § 1.1.

[373] *See* Letter from J.F. Walsh to G. Hobart (Aug. 13, 2014) at 7; *see also* W. De Gutierrez-Mahoney Deposition at 249:11- 250:8.; Email from Tom McDonald to Tom Smith, *et al.*, RE: Clarifying the "partial" issue in CSMP (Jun. 10, 2010), MCKMDL00633917.

[374] *See* ISMC CSMP Manual 2015 at 31, § 6.1.II.A.

[375] *Id.* at 33.

[376] *Id.* at 32-34 (Figure 7: AA00 Family Code -Default Thresholds).

[377] *See* McKesson Regional Statistical Norms 2/24/2014 at 2 (By February 2014, the average number of doses (3 months rounded) was 24,500 units for both hydrocodone and oxycodone or more than 8,100 units per month); *see infra* LDMP discussion at section 3.2.5.2.

pharmacies starting out at or above the DEA's prior 5,000 dosage unit average threshold level for hydrocodone.[378]

McKesson also set thresholds for existing customers [redacted] However, the Manual failed to indicate what constitutes "recent" dispensing history (e.g., 3 months, 6 months, 12 months, etc.). This "loophole" potentially allowed the DRA to cherry-pick the depth of the history to achieve the "best" results allowing McKesson to "justify" a potentially high threshold and avoid dealing with a threshold excursion.[380]

Basing the thresholds on [redacted] also fails to account for the fact that pharmacy dispensing history was and is artificially high as a result of the overprescribing of opioids. Therefore, basing thresholds on [redacted] will not reduce opioid dispensing to "pre-epidemic" levels.

Finally, the way the CSMP was structured, McKesson was not looking for suspicious orders, but instead for suspicious *customers*.[381] However, DEA clearly informed McKesson that such an approach was contrary to both the CSA and the DEA regulations[382] and it appears this was just a rationalization McKesson used to avoid its reporting obligations.[383]

Regardless of which type of threshold is used (new versus existing customer), or whether McKesson actually was looking for suspicious customers and not orders, the methodology employed by McKesson was flawed from the start and resulted in the thresholds being an ineffective control from a diversion prevention perspective.

B. Threshold Buffers

McKesson further weakened the value of using thresholds as a diversion prevention tool by factoring in "buffers." These "buffers," while not expressly defined, were described generically in both the 2011 and 2013 CSMP Manuals.[384] Buffers were additional quantities added to the base threshold level. According to the government and Mr. de Gutierrez-Mahoney, the company's *sub rosa* practice was to set a buffer of 10%, which was added to the highest number of dosage units purchased in a single month over the previous 12 months to

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[378] *See* P.C. Julian 1/18/2006 letter to J.T. Rannazzisi at 3-4 ("DEA has stated that monthly sales of over 5,000 dosage units of hydrocodone should be used as a flag to whether the pharmacy is dispensing legitimate prescriptions."); *see also* Walker Internet Presentation at 4.

[379] *See* ISMC CSMP Manual 2015, at 31, § 6.1.II.B. The Manual described the Customer Script and Dose analyzer as an "[a]nalytical tool that enables DRAs [Directors of Regulatory Affairs] to evaluate pharmacy's [sic.] dispensing patterns over a period of time to determine whether any red flags exist." *Id.* at 25, § 5.2.3.1.

[380] *See* N. Hartle, Deposition at 125:9 to 126:17.

[381] *See* W. Ihlenfeld 3/20/2014 letter to G. Hobart at 1.

[382] *Id.* at 3.

[383] *Id.* at 1.

[384] *See* CSMP Manual 2011, *and* CSMP Manual 2013, at § 1.1; *see also* J.F. Walsh 8/13/2014 letter to G. Hobart at 7.

create the finished threshold.[385] The intent in setting thresholds this way was that most of McKesson's customers would never reach their established thresholds.[386]

However, even applying a 10% buffer was not consistent within McKesson. In September 2014, Nathan Hartle advised Michael Bishop, a Regulatory Affairs Manager, to use a 25% buffer writing "[w]e have used 25% in the past so that is what I would put in for now."[387] In his deposition, Mr. Hartle attempted to justify the use of the buffer by arguing that " there is significant variation in purchasing patterns at times."[388]

This justification does not make sense. If McKesson needed a 25% buffer to account for purchasing pattern variations that suggests McKesson really did not know their customers as they were charged with doing by the DEA. On the other hand, if McKesson did know their customers and still applied the 25% buffer that suggests McKesson was avoiding the need to address potential diversionary conduct with their customers, which also is contrary to the SOM requirements. In either case, McKesson was not in compliance with federal SOM requirements and expectations.

Furthermore, McKesson was already aware that its threshold numbers were high and adding the "buffer" only compounded the situation by reducing further the number of potential suspicious orders. In fact, six years earlier when planning for the initial CSMP roll-out in March 2008, the Regulatory Affairs team noted that 22.7% of their customers purchased more than 10,000 dosage units of hydrocodone per quarter, with 6% purchasing between 20,000 and 50,000 dosage units per quarter with some going as high as more than 200,000 dosage units.[389] These numbers alone indicated that potentially as many as 1,500 (25,000 total customers x 6%) of McKesson's controlled substances customers were diverting hydrocodone. In August 2011, Dave Gustin, a Director of Regulatory Affairs ("DRA"), raised similar concerns about the thresholds being too high:

> I have thought of an area that needs tightening up in CSMP, and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases). The increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline that may be being used for legitimate reasons…. If you look at the lists, you may be able to make the call to reduce some thresholds based on your or the sales person's knowledge of the acct."[390]

McKesson, however, appears not to have applied significant effort to address the threshold over-inflation until 2015, when this effort resulted in sizable threshold reductions for many customers.[391] Those sizable reductions

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[385] See W. De Gutierrez-Mahoney Deposition at 249:11 to 250:8; *see also* J.F. Walsh 8/13/2014 letter to G. Hobart at 7.

[386] *See* T. McDonald 6/10/2010 email to Tom Smith, MCKMDL00633917.

[387] Email from N. Hartle to M. Bishop, *et al.*, *Wakefern Threshold Methodology* (Sept. 9, 2014), MCKMDL00430124.

[388] N. Hartle Deposition at 200:4-8.

[389] Email M. Oriente to D. Walker, *et. al*, Regulatory Meeting 3/5 & 3/6, Attachment at 7 (Mar. 7, 2008), MCKMDL00545048 at MCKMDL00545054.

[390] *See* Email from D. Gustin to D. Fagerskog, *et al.*, a couple of attachments were not sorted right. Here they are again. Project for the next few weeks., (Aug. 31, 2011), MCKMDL00507799.

[391] *See* Memorandum from N. Hartle to File, *McKesson's Controlled Substance Monitoring Program Oxycodone Threshold Reduction Report* (Feb. 9, 2015) (reducing oxycodone thresholds on 2,624 RNA customers), MCKMDL00402184; *see also* Email from N. Hartle

indicate that McKesson knew its thresholds were not set properly to identify suspicious orders and prevent potential diversion situations from occurring.

C. Threshold Disclosures

As part of the effort to ensure that the CSMP was customer-friendly and allowed "McKesson customer[s] [to] continue with business as usual,"[392] McKesson began preemptively telling customers they were approaching their threshold limits and at risk for order blocking.[393] Doing so undercut the effectiveness of the thresholds as customers, whether diverting or not, were warned of the impending limit giving them time to request a threshold increase so that the threshold was not triggered. In fact, the following justification was stated internally for creating the threshold warning report in the first place:

> We are in the business to sell the product. If we could produce a report … that warned customers approach to the threshold, say at 85% of their 10,000 dosages, work could begin on justifying an increase in threshold prior to any lost sales.[394]

Helping customers avoid thresholds and order blocking are not objectives of a legitimate SOM program. Maintaining effective controls to prevent diversion, as well as identifying and reporting suspicious orders, should instead be the goal.

The standard for notification appears to be when the customer reached approximately 90% of their threshold.[395] Although McKesson was not supposed to share the threshold with the customers, even if the customers were not told what their threshold was, they could back into the number with a bit of effort.[396] The rationale for not telling customers exactly what their thresholds were was "so that they can't try to manipulate a way around it, right, and get drugs from other suppliers or other distributors or something like that."[397]

Customers, in fact, did not always have to back into their thresholds; they simply got them from their Distribution Center sales team. While the CSMP Manual states that notice of the impending threshold limit would be shown on the customer invoice, and as Mr. Hartle acknowledged, there was sound policy for not

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to K. Peck, FW: Threshold Reduction Initiative – 9143 and 9144 (May 1, 2005) (reductions for ISMC customers), MCKMDL00410744.

[392] Email attachment from D. Walker to Bill de Gutierrez-Mahoney, *McKesson* Controlled Substances Monitoring Program – Program Guide for Pharmacies, 2 (Apr. 4, 2008); *see also* Email D. Walker to #PGVDO, *et al.*, List 1 Chemicals (Jun 3, 2010) ("There will no longer be "partial" omits of controlled substances or List 1 chemicals. If a customer exceeds their threshold on a certain item the entire item ordered will not be shipped."), MCKMDL00633917 at MCKMDL0063919.

[393] *See* CSMP Manual 2011 at § 2.

[394] *See* Email from S. Mackarness to G. Hillard (Oct. 26, 2006), MCKMDL00543971 at MCKMDL00543972.

[395] *See* N. Hartle Deposition at 135:7-13.

[396] *See* N. Hartle Deposition at 136:1-8.

[397] *See* N. Hartle Deposition at 134:15-18.

providing threshold details, the CSMP provided a large loophole for customers to learn about their thresholds.[398]

The CSMP Manual also required the Directors of Regulatory Affairs ("DRAs") to notify the Distribution Center's management and sales of the threshold warning and the Manual provided that the sales team had the discretion "to contact the customer to discuss the threshold levels."[399] The outcome is predictable given Distribution Center personnel had a powerful incentive to provide that information because "they're paid on keeping customers and making sales."[400]

For example in April 2013, Amanda Miller, RNA Account Manager in Support Solutions, sent Melanie Petropoulos, Vice President, Pharmacy for Marc Glassman, Inc. a copy of the internal system print out showing their oxycodone threshold, the monthly purchases on record and the percentage of thresholds used for three Glassman entities.[401] This was not an isolated instance,[402] as the sharing of thresholds started almost as soon as the CSMP program was instituted.[403]

It also seems that Regulatory Affairs did not always follow the rule that thresholds should not be shared. For example, in April 2008, Mr. Walker, head of the SOM program, wrote in an email that he was not opposed to honor a customer's request for "a breakdown of our current thresholds on our controlled substances for each site" because he was sure that "we will get a lot of these requests from customers wanting to make sure we have it covered."[404]

Overall, McKesson's "proactive" approach of communicating threshold warnings to customers effectively rendered the thresholds meaningless as a diversion prevention goal. This was further exacerbated by the policy of allowing Distribution Center personnel to contact and discuss the actual threshold amounts with customers. Thus, the employees the CSMP program who were counted on to be the "eyes and ears" of the program and who were on the front lines, were rewarded not for spotting and stopping suspicious orders, but for making sure the SOM program did not stop customer orders and disrupt business, thereby undermining the CSMP as a diversion prevention control.

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[398] *See* CSMP Manual 2011 at § 2.1.

[399] *See id.*

[400] N Hartle Deposition at 138:1-16.

[401] *See* Email from Amanda Miller to Melanie Petropoulous, CSMP 4/23/13 (Apr. 23, 2013), MCKMDL00476776.

[402] *See, e.g.,* Email from Denise Joslyn to Joseph Lahvoich, Acme 1/11/2013 CSMP (Jan. 11, 2013), MCKMDL00496271; Ned McKenna, *et al.*, *CVS CSMP: Threshold Review*, 9 (Jan. 9, 2009), MCKMDL00574488 at MCKMDL00574496 ("McKesson will manage reasonable threshold requests for CVS as needed…"); Email from Sabrina Cook to Gregory Carlson, Giant Eagle CSMP Thresholds (Oct. 22, 2008), MCKMDL00628660.

[403] *See* Sabrina Cook 10/22/2008 email to Gregory Carlson.

[404] Email from D. Walker to W. De Gutierrez-Mahoney, *et al.*, FW: NEW DEA ORDERING STANDARDS (Apr. 17, 2008), MCKMDL00543610.

D. Exceeding the Threshold (TCRs and Level 1-3 Review)

Similarly, McKesson's program and practices also undercut the controls associated with when orders are deemed "suspicious" (e.g., order blocking). According to the CSMP Manual, once a customer met or exceeded the threshold, known as a "threshold excursion," the order and all subsequent orders were blocked ("omits").[405] Orders could only be unblocked if threshold was temporarily or permanently changed, the product is returned so that the threshold is no longer exceeded, or the new month starts, and the threshold resets.[406] Exceeding the threshold also triggered the SOM Level 1-3 review process, which was adopted from the LDMP.[407]

Although conceived as a controlled, documented way to make appropriate adjustments to thresholds, the Threshold Change Request ("TCR"), like any internal control, could be abused, which it was in McKesson's case. For any control, once the exceptions or changes become commonplace, the control is rendered ineffective. In the case of thresholds, TCRs were commonplace at McKesson.[408] The solution when this occurs is to change the control or disallow exceptions, not to simply keep processing exception requests.

Per the CSMP Manual, threshold changes could either be temporary (i.e., for that month) or permanent.[409] DRA approval was needed for the TCR to become effective and that approval under the CSMP program was considered a Level 1 review, which now included both TCRs and threshold excursions.[410]

There was also a provision for Emergency TCRs, but like other crucial terms in McKesson's program, there is no definition or guidance as to what constitutes an "emergency" necessitating a two-hour review.[411] It also is not clear that Emergency TCRs were needed given that DRA approvals were generally done "the same day."[412]

Under the CSMP, the Level 1-3 review process could be avoided entirely if the customer requested a TCR before the threshold excursion occurred.[413] Therefore, it was a relatively common practice for Distribution Center personnel to contact the customer upon receiving a customer threshold warning and put through a TCR.[414] For example, as discussed above, Amanda Walker provided the VP of Pharmacy for Marc Glassman, Inc. their threshold numbers and current purchasing levels with the brief note "Let me know if you need to

[405] *See* CSMP Manual 2011 at § 2.2; *see also* D. Walker 6/3/2010 email to #PGVDO, *et al.* ("There will no longer be "partial" omits of controlled substances or List 1 chemicals. If a customer exceeds their threshold on a certain item the entire item ordered will not be shipped.").

[406] *Id.*

[407] *See* CSMP Manual 2011 at §§ 2.2.1-2.2.4; N. Hartle Deposition at 140:4-16.

[408] *See* Email A. Miller to D. Graziano, RE: CSMP 4/23/13 (Apr. 24, 2013), MCKMDL00476776.

[409] *See* CSMP Manual 2011 at § 1.3.1.

[410] *Id.* at § 1.3.1

[411] *See* CSMP Manual 2011 at § 1.3.2.

[412] *See* Email from A. Miller 4/24/2018 to D. Graziano.

[413] N Hartle Deposition at 125:9-24.

[414] *See* S. Mackarness 10/26/2006 email to G. Hillard ("If we could produce a report … that warned a customers [sic.] approach to the threshold … work could begin on justifying an increase in threshold prior to any lost sales.").

make any adjustments."[415] As was the case with threshold disclosures, using TCRs to avoid triggering the suspicious order process through continually raising the bar was widespread.[416]

By using Distribution Center personnel to solicit in advance whether a threshold increase was needed and to facilitate TCRs, McKesson eviscerated its own diversion control by ensuring that customers avoided triggering order blocking, as well as suspicious order reporting and investigations. In short, McKesson employees used TCRs to manipulate the SOM process to prevent lost sales.[417]

E. Customer Due Diligence or Level 1 Review

Another critical part of the SOM program (or any compliance program) is conducting due diligence on third parties (suppliers, vendors, business partners, and customers) to avoid engaging or working with so-called external "bad actors."[418] Customer due diligence under the CSMP also was important and was used as part of the threshold setting process threshold excursions and TCRs.[419] However, although McKesson's due diligence process looked functional on paper, McKesson's implementation of the program made it a *pro forma* exercise.

As part of the onboarding process for customers, a background questionnaire was required from the customer, especially for ISMC (the smaller) customers, as part of the threshold setting process.[420] The questionnaire, however, was heavily biased towards vetting the customer's financial profile such as overall prescription and controlled substances purchasing patterns, as well as the pharmacy's customer base, instead of their overall compliance stance.[421] For example, the questionnaire asked the customer whether they were subject to any regulatory enforcement actions and it did not require the DRA to "GOOGLE" the customer to see if there was any relevant information in the public domain. Therefore, McKesson limited the inquiry to what the customers chose to supply, with little or no attempt at independent verification. [422]

McKesson's interactions with Tug Valley Pharmacy aptly illustrate the problems with this approach. In May 2015, McKesson received a new customer questionnaire from Tug Valley in which the pharmacy disclosed that Miami-Luken had terminated its ability to purchase controlled substances.[423] McKesson also learned that Tug Valley was involved in pending litigation relating to allegations of controlled substances diversion.[424] However, despite this knowledge, McKesson approved Tug Valley's application in July 2015.[425] In January

[415] *See* Amanda Miller 4/23/2013 email to Melanie Petropoulous.

[416] *See* J.F. Walsh 8/13/2014 letter to G. Hobart at 12.

[417] *See* S. Mackarness 10/26/2006 email to G. Hillard.

[418] *See, e.g.,* James Arnold 6/2013 presentation at slides 42-53); Diane Murphy, *The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics*, 87 Iowa L. Rev. 697, 703 (2002).

[419] *See* CSMP Manual 2013 *and* CSMP Manual 2011 §§ 1.3.1, 2.2 and 3.

[420] CSMP Manual 2013 at § 1.2.2.

[421] *See* CSMP Manual 2013 at § 3.

[422] CSMP Manual 2013, at, § 3.2.1 and § 3.2.2.

[423] *See* W.Va. Red Flags Report at 142.

[424] *Id.* at 147

[425] *Id.*

2016, McKesson suspended Tug Valley after a *CBS News* report focused on the role distributors in the opioid crisis and "prominently featured Tug Valley".[426] Tug Valley submitted a new application in February 2016 representing that the pharmacy was under new ownership, and while the questionnaire lacked answers to many of the crucial questions, the McKesson Regulatory Investigative Report found no "red flags."[427] McKesson also learned that the former owner still had a security interest in the pharmacy, which supposedly was under new ownership.[428] Once more, despite the existence of new "red flags," McKesson reinstated the pharmacy.[429]

Red flags, like the ones that should have been detected with Tug Valley Pharmacy, were first addressed in the 2015 CSMP Manual. [redacted][0] It also required the DRA to conduct a further inquiry if a "red flag" was identified, but gave the DRA wide discretion in determining what that further inquiry entailed.[431] [redacted], incorporated the same concepts found in the DEA's list of "circumstances that might be indicative of diversion" published in 2006.[432] Thus, McKesson should not have waited until 2015 to start using these "red flags."

No due diligence tools (e.g., questionnaires, licensing verifications, debarment checks, etc.) will be effective if the people charged with reviewing the data gathered and presented fail to provide an appropriate "check and balance" (i.e., compliance) function. In the case of McKesson's SOM program, in addition to the Distribution Center employees being compromised by their involvement in the TCR process, Distribution Center management and Regulatory Affairs on many occasions simply failed to exercise any meaningful oversight or challenge missing data and "flimsy rationales."

The failure to conduct meaningful oversight or challenge "flimsy rationales" was systemic across the McKesson network as confirmed on multiple occasions by DEA and DOJ officials in various communications.[433] McKesson, itself recognized the issue, but allowed these practices to continue without ensuring appropriate changes occurred with predictable results; decisions to increase customer thresholds were made without an apparent rational basis.[434]

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[426] *Id.* at 145 and 147.

[427] *Id.* at 149-150.

[428] *Id.* at 153.

[429] *Id.* at 276.

[430] *See* ISMC CSMP Manual 2015 at 18-22.

[431] *See* ISMC CSMP Manual 2015 §§ 5.1.I.B to 5.1.II.

[432] *See* DEA 9/27/2006 Letter at 3.

[433] *See, e.g.,* J.F. Walsh 8/13/2014 letter to G. Hobart); D. Cutteman, *et al.*, 11/4/2014 letter to G. Hobart; W. Ihlenfeld, II 3/20/2014 letter to G. Hobart.

[434] *See, e.g.,* Email from D. Gustin to D. Fagerskog, *et al.*, CSMP Contribution, DCM Call, Tightening up our increase process (Apr. 15, 2011) ("We also need to tighten up the process regarding granting increases. We have gotten to the point where certain % of increase [sic.] are almost automatic and where we are too easily accepting of 'reasons' like 'business increase' for raising thresholds by small amounts."), MCKMDL00507221 at MCKMDL00507223; *see also* B. Russell email to B. de Gutierrez-Mahoney, *et al.*, *Threshold Change Requests* (Jul. 27, 2012) (citing email from T. McDonald in Regulatory Affairs on how to appropriately document TCRs); MCKMDL00633455.

This persistent lack of oversight of customer behavior perhaps is best illustrated by the New Castle, Pennsylvania distribution center, which served parts of West Virginia as well as Cuyahoga and Summit Counties in Ohio. From 2000 to the present, Blaine Snider, a 39-year McKesson employee, has been New Castle's Director of Operations.[435] Mr. Snider, as the Director of Operations or Distribution Center Manager ("DCM"),[436] was supposed to raise concerns about potentially suspicious customer orders and ultimately could refuse shipments to those customers he believed were placing unjustifiable suspicious orders.[437] He has, in fact, done neither during his tenure.

1. The "Thanksgiving" Increases

Perhaps the most egregious example of failed oversight and due diligence occurred in December 2008 and involved Mr. Snider, Dave Gustin, DRA and Michael Bishop. On November 28, 2008, a request was sent to change more than 200 RNA account thresholds to Micheal Bishop, Compliance Analyst Business Process, RNA Support Solutions.[438] The form lists "various RNA customers" including Wal-Mart, Rite Aid and Target on an attachment and lists the controlled substances requested as "various."[439] A permanent 30% threshold increase was requested and the reason for the change was listed as, "Increase due to Thanksgiving holiday – 30% increase." When asked about the Thanksgiving holiday increases in his deposition, Mr. Snider testified it was McKesson's policy to grant <u>permanent</u> threshold increases based on holidays.[440]

Mr. Bishop, in turn, passed the request to Dave Gustin, Director of Regulatory Affairs, who simply made the changes before processing the paperwork. As a result, Mr. Gustin emailed Bishop on December 16, 2008, requesting that Bishop provide a "TCR from you signed and dated the 30th. I will use it for the 30% increases I made for the RNAs that day after you emailed me all those reports."[441] On December 17, 2008, Mr. Gustin confirmed with Bishop that these were the "Thanksgiving increases" that occurred on November 28th.[442]

Not only was this 30% increase put through as a permanent versus perhaps a temporary request, but also the rationale of the Thanksgiving holiday was arbitrarily applied to 200 accounts by the DRA. To justify his actions in not performing the required reviews prior to making the changes, Mr. Gustin wrote that he "was the only DRA on and so my time was spent making the changes."[443] Furthermore, it appears that his request to "backdate" the TCR form as part of a larger and more commonplace practice within McKesson's Regulatory Affairs function. According to Nathan Hartle, "it's standard to document things after. You may make the

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[435] *See* B. Snider Deposition at 19:4-13. According to Snider, the terms Director of Operations and Distribution Center Manager ("DCM") are used interchangeably at McKesson.

[436] *See id.* at 121:1-4.

[437] *Id.* 108:2-17 and 109:17:22.

[438] *See* Blaine Snider, *Threshold Change Request Form*, (Nov. 28, 2008), MCKMDL00363951 at MCKMDL00363954.

[439] *See id.*; Attachment is found at MCKMDL0036953.

[440] *See* B. Snider Deposition at 223:22-24 and 224:1-10.

[441] *See* Dave Gustin email to Michael Bishop, RE: could you do me a favor (Dec. 16, 2008), MCKMDL00000522.

[442] *See* Dave Gustin email to Michael Bishop, RE: could you do me a favor (Dec. 17, 2008), MCKMDL00000521.

[443] *See* Dave Gustin email to #PGDCM, *et al.*, FW: could you do me a favor (Dec. 17, 2008), MCKMDL00363951 at MCKMDL00363955.

decision based on the information you have in your own notes. To put into the format may happen after that. That's not uncommon."[444] Mr. Hartle also stated, "you make decisions based on your notes and do the official documentation later."[445] To be clear, "backdating" is never acceptable, especially when it involves regulatory documentation. Furthermore, the "Thanksgiving" threshold increases were not the only instance where improper due diligence was conducted concerning controlled substance orders by McKesson customers.

2. Retail National Account Deference

The Thanksgiving increases are symptomatic of a broader pattern of conduct by McKesson that involved deferring to the retail national account ("RNA") customers to police their own pharmacies, thereby mistakenly absolving McKesson of the need to apply its SOM program to those accounts. For example, within the documents produced by McKesson, there are numerous examples of Retail National Account ("RNA") stores in Summit and Cuyahoga Counties being granted threshold increases with little or no investigation or interrogation.[446]

McKesson's actions with RNA customers run contrary to its regulatory obligations and are inconsistent with the actions of a reasonable and prudent distributor because controlled substances compliance is not deferrable or delegable.

McKesson's Senior Director of Distribution Operations, Donald Walker, readily acknowledged that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.[447] For example, as seen in a January 2009 presentation, McKesson outlined its plan for automatic threshold increases for CVS stores when they approached their threshold and to only seek a justification for thresholds increases from CVS if the increases were "extraordinary" and without "further CVS explanation."[448] McKesson's erroneous reasoning for such automatic threshold increases was to "minimize disruption of business," and to ignore reviewing "routine" threshold increases.[449]

9.5.7 McKesson's Internal Audit process was ineffectual and not a reasonable control to detect non-compliance.

McKesson's Board of Directors in April 2018 publicly released a report by a Special Committee of the Board that examined the company's oversight of opioid distribution by senior management and the Board during the

[444] *See* N. Hartle Deposition at 166:1-6

[445] *See* N. Hartle Deposition at 165: 9-11.

[446] *See e.g.,* Giant Eagle 4030 Due Diligence File, MCKMDL00555448; Email from S. Cook to D. Gustin, *et al.*, RE: Pain mgt, (Nov. 1, 2010), MCKMDL00512974; Email from D. Gustin to S. Cook, FW: Giant Eagle CSMP Thresholds, (Feb. 23, 2009), MCKMDL00628614; Giant Eagle 6376 Due Diligence File MCKMDL00555473; Giant Eagle 0209 Due Diligence File MCKMDL00555484.

[447] *See* Donald Walker Deposition, 190-193 (Jan. 10, 2019).

[448] *See* Presentation by N. McKenna, *et al.*, *CVS CSMP: Threshold Review,* 2 (Jan. 9, 2009), MCKMDL00574488.

[449] *Id.*

time period between the two settlements with the federal government (2008 to 2017).[450] The Special Committee concluded that:

> the Committee's investigation revealed a strong moral culture at McKesson, as led by Senior Management and reinforced by the Board, and that the Company's Chief Executive Officer and others in Senior Management created a strong tone at the top of McKesson that encouraged ethical and compliant conduct.[451]

The Special Committee felt that the Audit Committee's and Senior Management's belief that the compliance program was satisfactory and working effectively was reasonable because the company "had oversight procedures in place, including Internal Audit reviews of the Company's compliance program and distribution facilities" and that there were "positive Internal Audit review results (including findings that management had addressed, or was addressing, any identified issues)."[452] My review of the details, however, revealed a very different picture.

I reviewed actual Corporate Internal Audit ("IA") reports of the controlled substances program and below provide a detailed discussion on those that occurred in 2007, 2010 and 2012.[453] As the Special Committee noted, for those audits the overall audit ratings were Green-Satisfactory, Yellow-Need Improvement, and Green-Satisfactory respectively.[454] However, in all three reports, IA either failed to probe the area deeply enough or failed to understand the importance of what they observed. In all three cases the risks were downplayed, which led to an overall audit rating and Executive Summary that conveyed a false sense that McKesson's SOM program was in compliance.

A. 2007 Report

In the 2007 report, the IA team noted issues with the LDMP program (Observation #1), the DEA Licensure Process (Observation #2) and Licensing Requirements policies and procedures (Observation #6).[455] All three observations involved a lack of formal processes, or guidance or training resulting in McKesson employees not knowing what was required of them.[456] All three observations were classified as being of "moderate" significance and none made it into the executive summary. This is in spite of the fact that a basic requirement of a controlled substances compliance program is to ensure that customers are lawfully entitled to receive shipments of controlled substances and that exceeding thresholds rendered orders potentially "suspicious" and

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[450] *See* MCK Teamsters Response at 4.

[451] *Id.* at 26.

[452] *Id.* at 28 and 29-30.

[453] *See* J. Robinson, *Audit Report- DEA Licensure and LDMP Audit U.S. Pharmaceuticals*, 08-SSPH-04 (Oct. 9, 2007), MCKMDL00591251; M. Fuller, *Audit Report – Distribution Center and Controlled Substances Monitoring Program U.S. Pharmaceutical Distribution Operations*, 10-SSPH-11 (Jul. 20, 2010), MCKMDL00591972; M. Fuller, *Audit Report – Distribution Center Audit U.S. Pharmaceutical Distribution Operations*, 12-SSPH-08 (Apr. 10, 2012), MCKMDL00594099. ["IA Report (year)"].

[454] *Id.*

[455] *See* IA Report 2007 at 7-9.

[456] *Id.*

thus reportable to the DEA.[457] In other words, being out of compliance with DEA regulations or not knowing them at all was not deemed a critical observation worthy of senior management's or the Board's attention.

B. 2010 Report

The 2010 report highlighted the fact that four Distribution Centers (Memphis, Lakeland, Phoenix, and Landover) were not following required processes in that required TCRs and Omit Reports were not being signed on a regular basis by the DCMs, which as the auditors noted, called into question whether the reviews were even being done.[458] However, just like the 2007 report, the observation was deemed to be of "moderate" significance and was not highlighted in the executive summary even though threshold usage and monitoring were parts of the 2008 DEA settlement. The action plan from each Distribution Center was essentially "we'll do better" and make sure the paperwork is signed, which is a wholly inadequate response.[459]

Finally, it appears that IA confined its review to simply looking to see if the documents were signed and dated as required. There is no evidence that any of the rationales were examined to see if they passed a commonsense test (i.e., no Thanksgiving holiday rationales for permanent increases). Therefore, IA apparently undertook a limited transactional review.

C. 2012 Report

The 2012 audit report also looked at TCRs and Omit Reports and found missing TCRs, unsigned TCRs, and missing Level 1 review forms.[460] In short, the same issues that were seen in 2010. Also, in the case of Sacramento, TCR and Omit Forms were completed ahead of when they were due (e.g., front-loaded).[461]

Once more the observation earned a "moderate" significance score and was not highlighted in the Executive Summary. This occurred even though the observation and the Distribution Center responses were the same as in 2010 but involved different distribution centers. This fact should have triggered heightened concern that the documentation concerns were systemic and not being remedied by U.S. Pharma Regulatory Affairs. Once more it appears that IA did not examine any underlying rationales for the TCRs or the adequacy of the Level 1 data.

The deficiencies in the IA reports are such that it was readily apparent why the IA ratings of the controlled substances compliance program are diametrically opposed to what the DEA repeatedly uncovered and brought to McKesson's attention in the same time period. Thus, the IA process was ineffective and failed to provide senior management and the Board with a true picture of how the controlled substances compliance program was operating.

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[457] *See* 21 C.F.R. §1301.74(a) and (b).

[458] *See* IA Report 2010 at 9-10 (Observation #4).

[459] *Id.*

[460] *See* IA Report 2012 at 9-10 (Observation #4).

[461] *Id* at 9.

9.5.8 McKesson failed to undertake appropriate corrective actions to ensure its controlled substances program was compliant with its regulatory obligations.

Although the DEA repeatedly placed McKesson on notice before the 2008 settlement of its failures to maintain a SOM system, McKesson failed to rectify the situation. Nor did the company correct the situation after the 2008 settlement, which required the DEA to undertake a second enforcement action in 2017. This type of recidivist behavior and reoccurrence of similar misconduct, as noted by the FSGs, "creates doubt regarding whether the organization took reasonable steps to meet the requirements of this guideline" or in this case of the requirements of the CSA and its accompanying regulations.[462] It certainly makes clear that McKesson lacked an adequate corrective action process.

The same lack of an appropriate corrective action process is illustrated by the Internal Audit reports. Given the fact that IA continued to perform the same type of audits in the same way in the face of DEA's diametrically opposite findings, indicates that McKesson made little or no attempt to ascertain why IA and DEA were getting such different results and to make any necessary course corrections.

However, what is more troubling is that McKesson, beyond rewriting the CSMP manual, ultimately increased the program's complexity by splitting it in half and by only making other relatively minor alterations. In short, it seems McKesson did not undertake the more systemic actions needed to eradicate its previous culture. The Special Committee's 2018 report amply supports this lack of any "decisive steps" stating "the Committee's investigation revealed a strong moral culture at McKesson, as led by Senior Management and reinforced by the Board, and that the Company's Chief Executive Officer and others in Senior Management created a strong tone at the top of McKesson that encouraged ethical and compliant conduct."[463] The evidence reviewed in this report does not support that conclusion.

The Board continues to maintain that McKesson's senior management "attempted in earnest to meet the DEA's suspicious order reporting regulations, despite a lack of specific instructions or feedback as to the parameters of a program that the DEA would find acceptable."[464] Between the CSA, the DEA regulations, the general industry letters, the numerous private and specific letters to the company, and the 2008 Settlement Agreement, the DEA was clear about what its concerns were, what the Agency felt were McKesson's responsibilities, and where it felt McKesson was lacking. McKesson, however, did not decisively rectify matters. Therefore, with the 2017 settlement, DEA essentially removed McKesson's discretionary ability to design and operate the controlled substances program and tailor it to fit McKesson's company structure. Instead, the DEA substituted a highly detailed government-designed roadmap set out in the Compliance Addendum.

Therefore, I believe the answers to the questions outlined by McKesson's Board of Directors in terms of McKesson's senior management should be:[465]

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[462] *See* FSGs 2004 at § 8B2.1, Application Note 2(D).

[463] *See* MCK Teamsters Response at 26.

[464] *See id.* at 28.

[465] *See* MCK Teamsters Response at 5.

- **Did McKesson's senior management intentionally disregard, or turn a blind eye to, the Company's compliance obligations following the 2008 settlement?** There is enough evidence to demonstrate that senior management "turned a blind eye" by not providing adequate support, commitment, resources, or accountability regarding its opioid distribution operations, despite its 2008 agreement with the DEA and despite being put on notice to those deficiencies by the DEA between 2008 and 2017.
- **Did senior management act in bad faith or recklessly in connection with the Company's distribution of opioids?** At a minimum, senior management failed in its duty to exercise appropriate oversight and governance over the company's distribution of opioids. These failures were systemic and not confined to a few "rogue" Distribution Centers or "bad apple" employees, but instead permeated the entire program.
- **Did McKesson's senior management take advantage of the opioid crisis by encouraging or condoning shipments of opioids to customers it knew or should have known were diverting the drugs for illegitimate use?** Senior management clearly knew or should have known that many McKesson customers were purchasing opioids at ever increasing levels for which no rational basis for the increases had been established. Furthermore, when confronted by the DEA with evidence that this was happening, senior management persisted with a program it knew or should have known was defective and out of compliance with its regulatory obligations. In short, the company simply never looked for legitimate explanations the ordering patterns it encountered.
- **Did the Company prioritize revenue over compliance?** In my opinion, McKesson's continuing tacit endorsement of minimal compliance prioritized allowing its customers to continue "doing business as usual" (e.g., selling more opioids) over meeting its regulatory and compliance oversight responsibilities. As one McKesson Vice President simply noted, "[w]e are in the business to sell product."[466] Such widespread failures, including not equating good compliance with good business, in my experience, can only happen because of this type of an inappropriate "tone at the top."

Finally, as noted in the Internal Audit discussion, the Board's Special Committee and its outside law firm, even with the benefit of hindsight knowing what the DEA found, failed to identify and address the problem that important observations about the controlled substances compliance program in IA reports were not being highlighted for the Board. Therefore, despite an IA process which provided an inaccurate view of the state of the SOM program, the Board continued to see the IA process as a significant factor justifying its basic conclusion of no wrongdoing by McKesson senior officials, including Mr. Walker, the SVP in charge of the program from 1997 to 2015.

9.5.9 No evidence was presented that McKesson had a formal risk assessment process during the period.

Without belaboring the point, McKesson also did not implement an adequate or formal risk assessment process involving controlled substances distribution. In fact, no evidence was uncovered in this review to indicate that

[466] *See* Email Sharon Harkness to Gary Hillard, *RE: hydrocodone reports* (Oct. 26, 2006), MCKMDL00543971 at MCKMDL00543972.

McKesson ever established a formal risk assessment process during the review period. Had there been such a process, McKesson would have made changes and improvements to its controlled substances program on its own. However, as can be seen with the LDMP and the various iterations of the CSMP, McKesson only made changes in response to DEA's threat of initiating actual enforcement actions. Had there been such a proactive risk assessment process, the IA findings in the 2007, 2010, and 2012 reports would not have been deemed to be of "moderate" significance.

9.6 Program Changes (2014 to Present)

9.6.1 The AGI Engagement

McKesson "retained the analytics consulting firm Analysis Group, Inc. ("AGI") in 2014 to assist in evaluating and recommending analytics enhancements to the Company's program."[467] [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

A. The Multiple-Threshold Model

The output of AGI's efforts was [redacted]

[467] *See* MCK Teamsters Response at 24.

[468] *See* Analysis Group, Inc., *Suspicious Order Monitoring Threshold System for McKesson Independent Retail Customers – Description and Rationale*, 2 (May 12, 2017), MCKMDL00437057 ["AGI SOM Description"].

[469] *Id.*

[470] *Id.* at 5-6.

[471] *See* AGI SOM Description at 2.

[472] *Id.* at 3.

[redacted]

[redacted]

[redacted]

[redacted]

B. Non-Model Thresholds

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

9.6.2 McKesson's implementation of the AGI model.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

9.7 Accountability - Consistent Enforcement

McKesson, throughout the Review Period, failed to maintain and utilize appropriate disciplinary mechanisms either towards:

- customers, who routinely exceeded established SOM thresholds, or internal employees, who collaborated with customers to circumvent the threshold controls (i.e., "gamed the system"), or
- their supervisors, who either encouraged or ignored the inappropriate collaboration between McKesson employees and customers and
- their supervisors who failed to make the necessary improvements to the controlled substances compliance program for the program to meet McKesson's regulatory obligations as a controlled substances distributor.

McKesson also did not use reasonable efforts to avoid putting "bad actors" in substantial authority positions over its distribution of controlled substances. Thus, there simply was no evidence presented of there being real consequences for circumventing or ignoring SOM controls.

9.7.1 Despite repeated breaches of company policies and DEA SOM requirements, McKesson failed to discipline those involved.

McKesson's overall compliance efforts (controlled substances and corporate compliance) also were ineffective because the company failed to hold those involved with serious breaches of the federal controlled substances requirements accountable, and in at least one case even promoted one of the culpable individuals to a position of greater authority within the controlled substances program. The cases of Donald Walker, Blaine Snider, and William de Gutierrez-Mahoney are instructive.

A. Donald Walker

Donald Walker was McKesson's senior-most employee in direct charge of McKesson's controlled substances compliance efforts. As the Senior Vice President for Distributor Operations, Mr. Walker headed up the SOM program from 1997 to 2015 having retained his position after the first settlement. In 2015, after the government expressed misgivings about the accuracy of his representations to them about McKesson's program,[489] and a year into the second round of negotiations with the DEA, McKesson reorganized the SOM program and replaced him.

[489] *See* W. Ihlenfeld letter to G. Hobart, *McKesson Matter – Ongoing Settlement Discussions*, (Mar. 20, 2014).

B. Blaine Snider

Blaine Snider has been the Distribution Center Manager for the New Castle, PA distribution center since 2000. The New Castle distribution center is responsible for servicing customers in both West Virginia, as well as Cuyahoga and Summit counties in Ohio. Despite his clear breaches of McKesson's controlled substances policies discussed throughout this report, Mr. Snider continues in his role as New Castle's DCM to the present day.

C. William de Gutierrez-Mahoney

William de Gutierrez-Mahoney was Distribution Center Manager for the Lakeland, Florida distribution center from 2004 through 2008.[490] In 2008, he was promoted to Director of Regulatory Affairs for the Southeast Region[491] even though he had no prior regulatory affairs work experience.[492] The Lakeland distribution center was one of six distribution centers involved in the 2008 Settlement Agreement for failing to report suspicious orders in 2005, resulting in a license suspension and more than $13 million in civil penalties for McKesson.[493] Despite his involvement with Lakeland as substantial authority personnel, McKesson rewarded him with a promotion to Director Regulatory Affairs over the entire Southeast Region. In 2014, the Lakeland distribution center was again cited by the DEA for failing to report suspicious orders for a five-year period from 2008-2013[494] during the time Mr. de Gutierrez-Mahoney had responsibility for Lakeland as its DRA.[495]

9.7.2 McKesson also failed to consistently terminate customers found in repeated breach of the SOM requirements.

While there are numerous examples of this occurring, some of which are discussed earlier in this report, a case in point is McKesson's sales to Family Pharmacy Services ("FPS") as documented by the U.S. Attorney's Office for the Northern District of West Virginia. According to the U.S. Attorney's Office, McKesson in April 2012 notified the DEA that it had identified FPS as a suspicious customer and ceased sales of oxycodone to the pharmacy.[496] However, according to the government, McKesson resumed sales of oxycodone to FPS 21 days before the termination letter was sent to DEA.[497] Furthermore, McKesson sold 69,500 dosage units of oxycodone to FPS during the remainder of 2012 and a further 120,500 dosage units of oxycodone in 2013.[498]
Cardinal Health, Inc.

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[490] *See* W. de Gutierrez-Mahoney Deposition at 24:18-24 and 25:1-2.

[491] *See id.* at 25:3-10.

[492] *See id.* at 34:14-19.

[493] *See* 2008 MOA.

[494] *See* D. Cutteman 11/4/2014 letter to G. Hobart at 4.

[495] W. de Gutierrez-Mahoney Deposition at 25:17-21.

[496] *See* W. Ihlenfeld letter to G. Hobart, *McKesson Matter – Ongoing Settlement Discussions*, (Mar. 20, 2014) at 4.

[497] *Id.* at 5.

[498] *Id.* at 5.

10 Cardinal Health, Inc.

10.1 Background

Formed in 1979, Cardinal Health, Inc. ("Cardinal" or "Cardinal Health") describes itself as a "global, integrated healthcare services and products company providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices." [499] Cardinal is headquartered in Dublin, Ohio and employs "nearly 50,000 people" and has annual revenues of $137 billion.[500]

From a controlled substances perspective, Cardinal serves more than 26,000 pharmacies, and in the case of West Virginia, it was the largest supplier of controlled substances from 2005 to 2016.[501] As of its 2008 settlement with the government, Cardinal operated 27 distribution centers that handled controlled substances.[502] By 2012 that number had increased to 28.[503]

Cardinal Health's controlled substance compliance program also has changed over time correlating to various regulatory enforcement milestones. Beginning in the fourth quarter 2007 and continuing into the first quarter of 2008, Cardinal received four Orders to Show Cause and Immediate Suspension of Registration ("ISOs") from the DEA that ultimately resulted in the 2008 AMOA.[504] In 2012, Cardinal Health again entered into a settlement agreement with the government.[505] As discussed in detail below, at each enforcement milestone, Cardinal modified its program in response to those proceedings.

10.2 Executive Summary

My review of Cardinal's controlled substances compliance efforts from 1996 to 2008 reveals a consistent pattern of systemic failure to meet its regulatory and corporate governance obligations with respect to controlled substances. After the 2008 government settlement Cardinal expended energy in generating a controlled

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[499] *See* CARDINAL HEALTH, Fiscal 2018 Form 10-K, 3 (Sept. 2018).

[500] *See* CARDINAL HEALTH FACT SHEET, *Essential to care* (2018).

[501] *See* U.S. House Energy & Commerce Committee Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, 115th Cong., 243 (Dec. 19, 2018) ["W.Va. Red Flags Report"].

[502] *See* Administrative Memorandum of Agreement between the U.S. Department of Justice, Drug Enforcement Administration and Cardinal Health, Inc., 1 (Oct. 2, 2008), CAH_MDL_PRIORPROD_DEA12_00014414 ["2008 CAH AMOA"].

[503] *See* Administrative Memorandum of Agreement between the U.S. Department of Justice, Drug Enforcement Administration and Cardinal Health, Inc., 1 (May 14, 2012), CAH_MDL2804_02465982 ["2012 CAH AMOA"].

[504] *See* Letter from M. Leonhart, Order to Show Cause and Immediate Suspension of Registration, Auburn, Washington Distribution Center (Nov. 28, 2007), CAH_MDL_PRIORPROD_DEA12_00014414 at CAH_MDL_PRIORPROD_DEA12_00014430; Letter from M. Leonhart, Order to Show Cause and Immediate Suspension of Registration, Lakeland, Florida Distribution Center (Dec. 5, 2007), CAH_MDL_PRIORPROD_DEA12_00014414 at CAH_MDL_PRIORPROD_DEA12_00014434; Letter from M. Leonhart, Order to Show Cause and Immediate Suspension of Registration, Swedesboro, New Jersey Distribution Center (Dec. 7, 2007), CAH_MDL_PRIORPROD_DEA12_00014414 at CAH_MDL_PRIORPROD_DEA12_00014439; Letter from J. Rannazzisi, Order to Show Cause Stafford, Texas Distribution Center (Jan. 30, 2008), CAH_MDL_PRIORPROD_DEA12_00014414 at CAH_MDL_PRIORPROD_DEA12_00014444, ["[Facility Name][Year]ISO" or collectively "2007 ISOs"].

[505] *See* 2012 CAH AMOA.

substances compliance program. However, Cardinal's poor program design exacerbated by poor implementation ultimately defeated those efforts resulting in another government settlement agreement in 2012. Thus, Cardinal created a "paper program" that was neither effective for controlling diversion or identifying and reporting suspicious orders of controlled substances.

The program's failure cannot be attributed to one root cause. Both corporate culture and Cardinal's overreliance on technology played prominent roles. Cardinal's controlled substances compliance efforts did not have the necessary support and commitment of senior management and its Board of Directors. Despite the well-documented existence of the applicable compliance program standards for controlled substances and corporate compliance dating back to the 1970s; Cardinal did not make a concentrated effort to comply with those until 2008. Nor did Cardinal adopt a proactive approach towards compliance, even after its settlement in 2008. Cardinal's management simply did not act unless it was pushed to do so by the DEA, and then the company only did the minimum.

In the case of technology, Cardinal placed a premium on its analytical systems to detect suspicious orders and potential diversion, while neglecting the importance of the human element in making sense from the data outputs.

Despite creating the appearance of a documented and adequate suspicious order monitoring program, the reality was the SOM and anti-diversion programs simply did not work. Even George Barrett, Executive Chairman of the Board for Cardinal Health, reluctantly admitted as much. When asked by a House Energy and Commerce subcommittee whether Cardinal inquired about the reason for the higher drug order when a pharmacy goes over its monthly drug threshold, Barrett replied:

> "I think the thresholds probably should have been set with a different set of eyes. I've mentioned this notion of asking different questions. And I think today we'd probably set those quite differently. But I think at the time of those pharmacies you referred to, thresholds probably should have been adjusted down more quickly." [506]

When pressed further about whether Cardinal simply turned a blind eye to the impact of requested threshold increases even when the rationale did not make sense, Barrett responded:

> "I have no reason to question the good intent of those doing that kind of assessment. They were professionals. I think they were looking at the incoming order of prescribing. I think now we know some of that prescribing was driven by some behavior that we would have liked to have caught in the physician world."[507]

The program failed in part because Cardinal failed to embrace its affirmative duties under the CSA to create and maintain an effective program to prevent diversion. It also failed because Cardinal developed a program that was so convoluted and riddled with loopholes that Cardinal could avoid identifying orders as suspicious and continued supplying customers that it knew or should have known were engaging in diversionary behavior.

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[506] W.Va. Red Flags Report at 223, *citing* Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong at 108 (2018).

[507] *Id.*

10.3 Impact

Cardinal's activities in West Virginia are indicative of the results caused by these compliance failures. In the case of West Virginia, Cardinal told the House Energy and Commerce Committee ("E&C Committee") that it could not determine if the company submitted any suspicious orders from 2006 to 2012 to the DEA involving customers in the state, but from 2012 to 2017 that number spiked to 2,070 suspicious order reports.[508] From 2005 to 2016, Cardinal Health distributed approximately 366 million dosage units of hydrocodone and oxycodone to its West Virginia customers, of which approximately 174 million dosage units or 47.5% were delivered between 2006 and 2011, the period where zero suspicious order reports could be confirmed. However, just doing the math, 52.5% or 192 million dosage units were delivered between 2011 and 2017 indicating that even with Cardinal reporting suspicious orders to the DEA, the company's efforts had little or no effect on actual amounts of opioids being supplied to West Virginia.

Shipment patterns in Summit and Cuyahoga counties also are illustrative. Beginning in approximately 2000 and continuing through 2018, Cardinal consistently shipped at least 400,000 dosage units per month of oxycodone and hydrocodone into Cuyahoga County.[509] From 2000 to 2008 that amount steadily increased to a maximum of approximately 1.1 million dosage units monthly.[510] Although that has declined since 2015, the level has never dipped below the 400,000-dosage units per month level.[511]

The case of Summit County is more dramatic. From 1996 to 2015, with one minor dip, Cardinal shipped ever increasing dosage units per month ultimately reaching a level of more than 750,000 dosage units per month of oxycodone and hydrocodone.[512] Like Cuyahoga County, since 2015 the number of dosage units has declined but remains above 400,000 units per month.[513]

CareMed Pharmacy

The history surrounding CareMed Pharmacy was explored during Mr. Reardon's deposition. The documentary evidence shown to Mr. Reardon demonstrated that the pharmacy owner in 2008 informed Cardinal's Quality and Regulatory Affairs personnel (Messrs. Morse and Forst) through the new pharmacy questionnaire that CareMed purchased opioids from multiple distributors including Cardinal.[514] Despite Mr. Forst acknowledging

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[508] *See* W.Va. Red Flags Report at 244.

[509] *See* Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 51, 136 (Total Dosage of Oxycodone and Hydrocodone Shipped by Cardinal Health to Cuyahoga County, Ohio (Jan. 1996 to April 2018)).

[510] *Id.*

[511] *Id.*

[512] *See* Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 93, 178 (Total Dosage of Oxycodone and Hydrocodone Shipped by Cardinal Health to Summit County, Ohio (Jan. 1996 to April 2018)).

[513] *Id.*

[514] *See* S. Reardon Deposition at 404:21-24.

that he was aware of CareMed's use of multiple distributors, he allowed Cardinal to continue supplying CareMed resulting in a 609% increase in controlled substances purchasing over 13 months.[515]

CVS #219

According to the DEA, from January 2008 to December 31, 2011, Cardinal sold over 5 million dosage units of oxycodone to CVS #219 or on average 137,994 dosage units per month.[516] However, it appears that no on-site visit was conducted by Cardinal prior to February 2012.[517]

From June 2009 to September 30, 2010, CVS #219 routinely exceeded its monthly oxycodone thresholds in amounts ranging from 6,310 dosage units in June 2009 to 94,100 units in August 2010.[518] At the same time, Cardinal approved threshold increases from 112,000 dosage units in June 2009 to a maximum of 235,000 dosage units per month from September 2010 with the notation that Cardinal did not see these amounts as unreasonable as to quantity, pattern or frequency. [519] However, Cardinal had clear evidence to the contrary.

In January 2010, Jennifer Hug, Manager of Retail National Accounts, wrote in an email that she "[s]poke with Nick at the pharmacy [and] [h]e stated that there are an increasing number of patients from pain clinics, but they are filing only for local clinics."[520] Upon receiving a response from Jason Spinard in CVS's Loss Prevention Department that CVS #219 was okay, Ms. Hug forwarded the information to Christopher Forst and Maranda Swedyk and Michael Moné saying "I wanted to forward to you the information from CVS's LP department, in reference to the **2 SOM Events** attached."[521] Ms. Hug recognized that the orders from CVS #219 were suspicious, but Cardinal continued shipping oxycodone to the store anyway.

On September 30, 2010, Mr. Moné received an email from Paul Farley about Mr. Farley's conversation with CVS about CVS #219, noting that the increased sales of oxycodone was the result of store closures in the area and that as a result of the DEA "cracking down on 'pill mills' … that is driving more legitimate traffic to CVS stores."[522] Mr. Farley also reported that CVS would not provide the doctor or patient information requested by Mr. Moné and that CVS did "not expect Cardinal to interrupt service to CVS stores since they have responded in the manner we agreed upon when launching the SOM program."[523] Despite the weakness of the response and refusal to provide information, Mr. Moné approved the CVS orders on hold because "[w]e will be working

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[515] *See* S. Reardon Deposition at 405:5-16.

[516] *See* Lakeland 2012 ISO at 2.

[517] *See* S. Morse Deposition at 117:13-17. (Morse although in charge of investigations and site visits did not know if a visit was conducted on CVS #219).

[518] *See* Cardinal Health Lakeland Thresholds Exceeded, CVS 219, CAH_MDL_PRIORPROD_DEA12_00004353.

[519] *Id.*

[520] *See* Email from J. Hug to J. Spinard, CVS 850 & CVS 219 – LP Research (Jan. 27, 2010), CAH_MDL_PRIORPROD_DEA12_00011836.

[521] *See* Email from J. Hug to M. Swedyk, C. Forst, M. Moné, FW: CVS 850 & CVS – LP Research (Feb. 15,2010) (emphasis added), CAH_MDL_PRIORPROD_DEA12_00011836.

[522] *See* Email from P. Farley to M. Moné, CVS #0219 (Sept. 30, 2019 (B. Jackson, SVP of National Accounts/Alternative Care was also copied on the email); CAH_MDL_PRIORPROD_DEA12_00003244 at CAH_MDL_PRIORPROD_DEA12_00003250.

[523] *Id.*

through another solution."[524] At the same the held orders were released, Cardinal increased CVS #219's oxycodone threshold by 37% (from 148,000 dosage units to 235,000 dosage units).[525] Finally, on November 10, 2011, Mr. Moné touted that Cardinal reduced the oxycodone threshold for CVS #219 to 45,000 dosage units per month, but neglected to put that into the context that Cardinal had already sold 5,000,000 dosage units to the store.[526]

The results of this pattern of systemic failure in Cardinal's anti-diversion program were entirely predictable. The amounts of opioids purchased, both legitimate and illegitimate, increased unabated for customers. Few, if any opioid orders, were deemed to be suspicious, investigated and reported to the DEA. Potential indicators that diversion was occurring were ignored.

10.4 Company Commitment – Compliance Culture, Organization & Resources

The evidence reviewed in this section demonstrates that Cardinal Health was and appears still not to be fully committed to meeting its regulatory obligations under the CSA and its accompanying regulations. As demonstrated by the culture, organizational structure and resourcing, compliance at Cardinal Health is secondary to management's focus on driving increasing revenues and cutting costs.

10.4.1 Cardinal's culture is myopically focused on increasing revenues and cutting cost while downplaying the importance of ethics and compliance.

In general, the Cardinal culture was and continues to be myopically focused on increasing revenues and cutting costs. Cardinal's new CEO, Michael Kaufman, wrote in his FY 18 annual report letter to shareholders that a 2019 fiscal priority was to be "laser-focused on our cost structure" and "[s]imply put, we are intensely focused on each dollar we spend."[527] He also stated that the company is focused on "[a] corporate culture that drives success," but what that translates into are "employees who are dedicated, hard-working and focused on the needs of their patients," in other words a "high-performing, accountable culture."[528] "We roll up our sleeves to get the job done [and] [w]e know how to pull together in good times and bad."[529] Compliance, ethics, and integrity are not found in Mr. Kaufman's stated vision of Cardinal culture. Instead, Cardinal Health's culture is all about the bottom line.

This lack of putting compliance first carries over into Cardinal's stated values. Cardinal values are:

1. We are **tenacious** in fulfilling our commitments to customers.

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[524] *See* Email from M. Moné to C. Forst (Sept. 30, 2010), CAH_MDL_PRIORPROD_DEA12_00003244 at CAH_MDL_PRIORPROD_DEA12_00003250.

[525] *See* Cardinal Health Lakeland Thresholds Exceeded, CVS 219, CAH_MDL_PRIORPROD_DEA12_00004353.

[526] *See* Moné Declaration at ¶ 45.

[527] *See* Cardinal Health, *2018 Annual Report*, 3 (Sept. 2018).

[528] *Id.* at 4.

[529] *Id.*

2. We are **accountable** for high performance and to each other.
3. We are **inventive** and **adaptable**.
4. We bring a sense of **optimism**, **enthusiasm** and a **competitive spirit** to our work.
5. We are **inclusive** and **work together** with confidence and trust.
6. We are **genuine**, **open**, **direct** and **respectfu**l.
7. We can be **trusted** to do the right thing.[530]

Compliance is not among the listed Cardinal values, and when it is mentioned in the Standards of Business Conduct, Cardinal frames acting "with integrity and in compliance with the law," within the frame of "[w]e work together, according to shared standards and values, to make wise decisions that foster a culture of trust and responsible conduct."[531] This suggests that Cardinal only complies with a law where Cardinal shares the same standards and values as the law, but not does not necessarily comply when the company disagrees with it. In short, compliance with legal requirements is optional.

This cultural lack of commitment to compliance appears to be historically consistent within Cardinal. For example, in 2008, then Cardinal CEO, Kerry Clark sent an email to all Cardinal Global Leadership Team ("GLT") members entitled "In the Penalty Box" to share some thoughts on regulatory compliance because "some of our failures in this area are burdening our financial performance and market capitalization."[532] Mr. Clark went on to formulate his theory that "we keep getting penalties-big penalties that are costing us customer loyalty, employee loyalty, and shareholder loyalty. Big penalties that are undermining our progress on the path to premier [sic.] against all three stakeholder groups."[533] He saw the weakness in the Cardinal culture as a lack of "accountability of leadership" that resulted in employees who "do not fully trust their leaders." Finally, he noted that "general managers are ultimately responsible for results [and] … are accountable for ensuring their units operate according to quality and legal/regulatory standards."[534]

However, that message of managerial accountability apparently did not take hold. In 2013, the McKesson team noted that "[p]erhaps the most surprising revelation [at the HDMA conference the prior week] was Steve Reardon and Gilberto Quintero saying Cardinal does not report suspicious orders to DEA … no upside."[535] Mr. Reardon was Cardinal's Vice President of Regulatory Operations, while Mr. Quintero was the Senior Vice President of Quality and Regulatory Affairs at Cardinal Health. Both were involved with overseeing and operating Cardinal's controlled substances compliance program.

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[530] *See* Cardinal Health, *Standards of Business Conduct*, 2 (2018) (emphasis in the original) at https://www.cardinalhealth.com/content/dam/corp/web/documents/fact-sheet/cardinal-health-standards-of-business-conduct-booklet-english.pdf.

[531] *Id.* at 6.

[532] *See* Email from K. Clark to GLT Communication, In the Penalty Box (Jan. 17, 2008), CAH_MDL_PRIORPROD_DEA07_00827893.

[533] *Id.*

[534] *Id.*

[535] *See* Email from W. de Guiterrez-Mahoney l to D. Walker, *et al*., HDMA notes (Mar. 11, 2013), MCKMDL00545341.

Based on the information I reviewed, it is readily apparent that Cardinal historically does not focus on or consider compliance with its controlled substances regulatory obligations particularly important, especially if this gets in the way of focusing on every dollar to maximize profits.

10.4.2 Cardinal failed to design an organizational structure with strong governance, made poor staffing choices and was slow to add resources to the SOM program demonstrating a lack of commitment to compliance.

During the review period, Cardinal has changed the structure of its controlled substances program several times. These changes correspond to Cardinal's various settlements with the government. However, while the Cardinal controlled substances program at times appeared robust on paper, in reality, it suffered from at least three underlying flaws: (a) a lack of strong senior management governance, (b) a slow commitment of resources and (c) poor choices of key operational staff.

Prior to 2007, Cardinal's central SOM organization was limited to three people, a vice president, and two managers.[536] The Vice President of Quality and Regulatory Affairs, Steve Reardon, reported directly to the President and CEO of PDPS, Mark Parrish.[537] In FY 2007 Compliance requested a 58% budget increase over FY2006 to add two FTE's (a manager and director).[538] In presenting the business case for the two new positions, Compliance told senior management that "[c]urrent department staff workloads are at full capacity, [e]ffective management of current projects and initiatives is difficult[, and] [r]esources to take on new initiatives and the ability to improve and enhance existing programs are lacking."[539] As Stephen Reardon Cardinal's Vice President Quality & Regulatory Affairs admitted in testimony, his staff could not investigate the volume of suspicious orders being identified.[540]

Starting in December 2007, with the approval of the two new positions, Cardinal slowly began increasing compliance resources. However, as described by Steve Lawrence the situation remained dire:

> We currently are working very hard to staff up our QRA group. Please understand that they are working day, night and weekends but they have been understaffed.[541]

Cardinal hired Craig Morford in 2008 to be its Chief Compliance Officer "with a mandate to establish a premier anti-diversion system."[542] On paper having the controlled substances program report to the Chief Compliance

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[536] *See* Board of Directors of Cardinal Health, Inc., *Investigation Report of the Special Demand Committee*, 7 (Apr. 12, 2013), CAH_MDL_PRIORPROD_HOUSE_0003331 ["Special Committee Report"].

[537] *See* Drug Distribution, *Compliance Budget Review Fiscal Year 2007*, 5 (updated), CAH_MDL2804_02102331 at CAH_MDL2804_02102334 ["FY 2007 Budget"].

[538] *Id.* at 3.

[539] *Id* at 2.

[540] *See* Stephen Reardon Deposition, 466:23-470:21 (Nov. 30, 2018).

[541] *See* Steve Lawrence email to G-NSA-Regional Directors, *et al.*, *FW: Threshold system and customer issues – Detailed summary so I apologize for the lengthy email*, 1 (Jan. 26, 2008), CAH_MDL_PRIORPROD_DEA07_00891487.

[542] *See* Special Committee Report at 9.

Officer, who in turn reports to the CEO gives the appearance that Cardinal took controlled substances compliance seriously. However, that appearance diverges from the reality of the inner workings at Cardinal. Beginning in 2009, Mr. Morford's attention was split as he became Chief Legal Officer as well.[543] Thus Morford was only fully engaged in establishing "a premier anti-diversion system" for 12 months. Mr. Morford's oversight role over the controlled substances program was further diminished with the hiring of Gilberto Quintero as Senior Vice President, Quality and Regulatory Affairs, who reported to Mr. Morford. While Mr. Quintero's hiring was necessary given the breadth of Mr. Morford's responsibilities, it is a further indication that Cardinal senior management provided tangential rather than direct oversight to the controlled substances program.

From 2008 to 2012, operational responsibility for the controlled substances program was vested in Michael Moné, Vice President, Anti-Diversion.[544] Mr. Moné in early 2008 hired Steve Morse and Christopher Forst as Directors of Supply Chain Integrity.[545] Their duties were split as follows:

- Morse was responsible for conducting investigations and site visits of customers, and
- Forst would handle the pharmaceutical analysis of customers.[546]

Therefore, in 2008, the central operational team for controlled substances compliance was still only 3 FTEs.

Cardinal very slowly increased headcount from 2010 to 2012. In 2010, Nicholas Rausch was added to the group as Director of Analytics and Information Management[547] By 2012, the central anti-diversion team consisted of 8 FTEs.[548]

As of 2012, Messrs. Moné and Morse were no longer involved with the anti-diversion team. According to the Special Committee, Mr. Moné was replaced because "evaluation[s] of customers and orders had been heavily focused on the clinical expertise and subjective judgment of the pharmacists in the anti-diversion group," while Mr. Morse was removed because he was "not as strategic as his former position required and there were questions about his judgment."[549] The removals of Messrs. Moné and Morse also coincide with Cardinal's 2012 AMOA.

From both an organizational design, as well as a resourcing perspective, Cardinal Health's failure to design an organizational structure with strong corporate governance together with its poor choice of staff and its slow commitment to add resources are consistent with the company's lack of focus on the importance of controlled substances compliance.

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[543] *Id.* at 9. According to Cardinal's official biography of Morford, his duties include responsibility for "Legal, Quality and Regulatory Affairs, Ethics and Compliance, Corporate Communications and Government Relations" *See* https://www.cardinalhealth.com/en/about-us/our-people/our-leaders/craig-morford.html.

[544] *Id.* at 8

[545] *Id.* at 8.

[546] *See id.* at 8-9.

[547] *Id.* at 9.

[548] *See* Organization Chart 2012-2015, P1.4592.

[549] *See* Special Committee Report at 34-35.

10.5 Program Core – Requirements, Education, Detection & Corrections

10.5.1 Viewed holistically, the core of Cardinal's SOM Program during the period ranges from incomplete to convoluted and inconsistent.

Overall the core of Cardinal's SOM program over the review period was either incomplete as it was before 2007, or too convoluted and inconsistent thereafter. In either case, it demonstrates that Cardinal failed to implement a program that was consistent with its understanding of its controlled substances obligations.

For the program pre-2007, the primary issue is that Cardinal artificially limited the focus of the program by concentrating only on reporting information to the DEA, rather than on its statutory obligation to prevent the product from being diverted. As a result, the pre-2007 system, as designed and implemented, was incomplete.

Cardinal's program from 2007 to 2012 was convoluted in that it was difficult to determine across the five key SOPs that comprised the program, where one ends, and the other begins. [550]

For example, it is unclear from the SOPs how the On-site Investigations and Detecting and Reporting Suspicious Orders and Responding to Threshold Events procedures operate together to form the suspicious order due diligence component of the program.

Additionally, some key definitions that comprise Cardinal's SOM program are not consistent across the various SOP's even though they are part of the same series (CAD-Cxxx). For example, the definition of "threshold event" (see table below) varies widely across the SOPs.

Table 1 Varying Definitions of "Threshold Event"

SOP	YEAR	DEFINITION
ON-SITE INVESTIGATIONS[551]	2009	An order for a regulated drug which exceeds the threshold set for a specific licensed customer.
SALES - ANTI-DIVERSION ALERT SIGNALS[552]	2009	Threshold Event Is defined as the initial held order created by a DEA#, Base Code, Threshold Limit combination.

[550] The four key SOP's are: Process to Establish SOM Threshold Limits, Sales-Anti-Diversion Alert Signals, On-site Investigations, and Detecting and Reporting Suspicious Orders and Responding to Threshold Events. *See* Cardinal Health, Process to Establish SOM Threshold Limits, HSCSQRA-CAD-C-002 (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0004208. In 2010 as the result of a restructuring, this document was renumbered as PDQRA-CAD-C002 via Document Control Notice ("DCN") 2555 (CAH_MDL_PRIORPROD_AG_0000017); Cardinal Health, Sales-Anti-Diversion Alert Signals, HSCSQRA-SAD-C003 (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0000323; Cardinal Health, On-site Investigations, PDQRA-CAD-C008 (Nov. 5, 2009), CAH_MDL_PRIORPROD_DEA12_00014535 ["Investigations SOP"]; Cardinal Health, Detecting and Reporting Suspicious Orders and Responding to Threshold Events, PDQRA-CAD-C007 (Jan. 6, 2012), CAH_MDL_PRIORPROD_AG_0000154 ["Reporting SOs 2012 SOP"]; Cardinal Health, Large Volume- Tactical and Analytical Committee Periodic Review Process, PRDQRA-CAD-C023 (Apr. 12, 2012), CAH_MDL2804_02288612 ["LV-TAC SOP"].

[551] *See* Investigations SOP at § 4.1.

[552] *See* Sales Alert SOP 2009 at § 4.1.

SOP	YEAR	DEFINITION
DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS[553]	2012	The initial held order for a regulated drug which exceeds the threshold set for the specified customer. This is created by a DEA#, Base Code and Threshold Limit combination.

10.5.2 Cardinal Health failed to understand that it and not the DEA was responsible for maintaining an effective program to detect and report suspicious orders and prevent diversion.

In 2012, Michael Moné, Vice President of Supply Chain Integrity, made a declaration that Cardinal repeatedly requested the DEA supply Cardinal with any information it had on Cardinal customers engaging in diversion.[554] For example, in October 2011, Cardinal's Chief Legal Officer, Craig Morford, asked DEA to provide that information and "Cardinal Health promised to immediately cease distributing controlled substances to any customer DEA so identified."[555] Mr. Morford stressed the issues of DEA's "[l]ess engagement with the industry," and "[l]imited guidance or notice" to Cardinal's Board of Directors Audit Committee meeting in November 2012.[556]

The declarations by Messrs. Morford and Moné demonstrate that Cardinal fundamentally misunderstood its obligations under the CSA. First, the CSA places an affirmative duty on distributors of controlled substances to maintain an effective program to prevent diversion.[557] Second, the CSA places no affirmative duty on the DEA to disclose any information to Cardinal regarding Cardinal customers engaging in diversion. Third, Mr. Moné's statement and Mr. Morford's presentation imply that because the DEA provided no information to Cardinal to "indicate that any of its customers was [sic.] diverting controlled substances," that diversion was not occurring.[558] Based on the evidence readily available to Cardinal, this was not the case.

10.5.3 Cardinal's early controlled substances program was not compliant with DEA regulatory requirements.

Cardinal's Board of Directors in November 2012 formed a "Special Demand Committee" to respond to a shareholder demand letter alleging that as evidenced by the 2012 AMOA, Cardinal failed to implement and

553 *See* Reporting SOs 2012 SOP at § 4.1.

554 *See* Cardinal Health, Inc. v. Eric Holder, Jr., et al, Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746 (Feb. 3, 2012) at ¶ 35, CAH_MDL_PRIORPROD_DEA12_00014053 at CAH_MDL_PRIORPROD_DEA12_00014067-68 [Moné Declaration]

555 *See id.*

556 *See* Presentation by C. Morford, *2012 Annual Quality and Regulatory (QRA) Report to the Audit Committee of the Board of Directors,* 8 (Nov. 2, 2012), CAH_MDL2804_03262274 at CAH_MDL2804_03262440.

557 *See generally* Section 5, *infra.*

558 *See* Moné Declaration at ¶ 35.

maintain systems to detect and prevent diversion as required under the CSA.[559] The Special Committee reported that prior to 2007, Cardinal focused its anti-diversion or AD measures on preventing price diversion and internet pharmacy diversion.[560] The Special Committee also noted that the controlled substances program had only a few employees dedicated to it, had no electronic order analyzer system, therefore, most of the customer and order information was paper-based and scattered.[561] Cardinal told a similar story to the House Energy & Commerce Committee ("E&C Committee") in 2018 and specifically acknowledged it was not until December 2008 that "Cardinal implemented formal anti-diversion Standard Operating Procedures (SOPs), which included SOPs for conducting prospective customer due diligence."[562]

Cardinal issued a Corporate Quality & Regulatory Compliance Standard Operating Procedures manual in June 2006 under the approval of Stephen Reardon, Cardinal's Vice President Quality & Regulatory Affairs.[563] At that time, the primary internal control was the use of the Ingredient Limit Report. The report, which was provided to the DEA on a monthly basis, identified customers that exceeded a pre-determined purchase level.[564] According to Mr. Reardon, the Ingredient Limit Report was used by Cardinal from approximately 1994 to 2008.[565]

The SOP manual described the Ingredient Limit Reports as "based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report."[566] However, the Ingredient Limit Reports only identified orders exceeding limits. They did not prevent the identified orders from shipping.[567]

In testimony to the E&C Committee, Cardinal stated that "'[t]he reports were generated based on a computer algorithm established by the DEA, which was meant to be used to calculate the quantity which, if exceeded in one month, constituted an order which may be excessive or suspicious.'"[568] Despite these descriptions, the methodology on how the limits were developed in Ingredient Limit Reports remains exceedingly unclear.

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[559] *See* Special Committee Report at 4-5.

[560] *Id.* at 7.

[561] *Id.* at 8.

[562] *See* W.Va. Red Flags Report at 115.

[563] *See* Cardinal Health, *Corporate Quality & Regulatory Compliance Standard Operating Procedures*, 1 (Jun. 15, 2006), CAH_MDL_PRIORPROD_DEA07_01188323 ["CAH 2006 SOP Manual"]. Prior to this manual, Cardinal had issued the DEA Compliance Manual a collection of documents that was "intended as a resource to the Controlled Substances Act and Regulations … [and] as a guide so that you can better understand DEA's function. Further, it is intended to help you learn to deal with the agency that has a tremendous impact on our business." *See* Cardinal Health, *DEA Compliance Manual* CAH_MDL_PRIORPROD_DEA07_01383895 at CAH_MDL_PRIORPROD_DEA07 _01383902.

[564] *See* Special Committee Report at 8.

[565] *See* S. Reardon Deposition at 411:20-23.

[566] *See* CAH 2006 SOP Manual, *DEA04.00 - Required Reports to DEA*, at 6 § 5(c).

[567] *See* S. Reardon Deposition at 427:12-23.

[568] *See* W.Va. Red Flags Report at 184.

However, according to Mr. Reardon, the limits were a combination of averages and multipliers to reach the final threshold limits.[569]

According to the SOP Manual, the distribution facility was required to monitor and identify "individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history" and "to notify the local DEA field office, if possible before the order [was] shipped."[570] Mr. Reardon testified that from 1994 to 2008 Cardinal relied on the "pickers and checkers" filling orders in the distribution center to identify the individual orders.[571]

Thus, DEA notification was the main purpose of Cardinal's SOM system prior to 2007. The program at that time did not require Cardinal employees to actively prevent suspicious orders from shipping. Employees merely needed to try to notify the DEA before the order shipped.

Therefore, as set out in the SOP Manual, Cardinal's controlled substances compliance program was not compliant with the DEA requirements as Cardinal employees were not expressly required to investigate "suspicious" orders or stop suspicious shipments to avoid potential diversion. Simply using thresholds to provide notices to the DEA does not constitute an operational program to prevent diversion. Thus, Cardinal's pre-2007 controlled substances compliance program efforts were not compliant as designed.

Cardinal's reliance on Ingredient Limit Reports and distribution center pickers did not work.[572] The chart below from DEA's Show Cause Order for Lakeland, Florida bears this out. The magnitude of the failure is especially egregious when contrasted against the fact that according to the DEA most retail pharmacists in Florida at that time were ordering less than 8,400 dosage units per month of hydrocodone.[573]

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[569] *See* S. Reardon Deposition at 442:12-16.

[570] *See* CAH 2006 SOP Manual at 6 § 5(d)(i).

[571] *See* S. Reardon Deposition at 428:10-24 and 429:1-2.

[572] *See* Lakeland 2007 ISO at 2.

[573] *Id.*

Table 2: Chart of Cardinal Florida Customers DEA Believed Were Diverting Hydrocodone[574]

Pharmacy	Total Dosage Units	Number of Months Distributions Made	Monthly Average	Dates of Distribution (*Distributions not made in every month)
Medipharm-Rx, Inc.	620,030	4	155,007	Aug – Dec 05*
DRM Enterprises, Inc.	929,600	22	42,254	Jan 06 – Oct 07
Jen-Mar Pharmacy Services, Inc.	353,700	11	32,154 1st 3 mos: 2,766 Last 8 mos: 43,175	Mar 06 – Feb 07*
Armenia Pharmacy, Inc.	132,900	12	11,075 1st 6 mos: 1,900 Last 6 mos: 20,250	Mar 06 – Feb 07
National Pharmacy, Inc.	659,800	9	73,311	Aug 05 – May 06*
Parulmed Corporation	468,400	20	23,420	Aug 05 – Apr 07*
Q-R-G, Inc.	1,213,200	5	242,640	Feb – June 06
RKR Holdings, Inc.	741,000	13	57,000	Aug 05 – Jan 07*
United Prescription Services, Inc.	1,148,100	4	287,025	Jul – Oct 06
Satellite Drug and Pharmacy	1,044,000	19	54,947 1st 4 mos: 375 Last 15 mos: 69,500	Feb 06 – Oct 07*

10.5.4 Cardinal's early training efforts were not fit for compliance purposes.

The Special Committee report described Cardinal's efforts to educate employees about controlled substances in the following terms:

> During Spring and Summer 2006, there were live training sessions for employees at six locations around the country, focused primarily on price diversion and diversion by internet pharmacies. The Company also developed and implemented two mandatory computer-based trainings in August and December 2007 for all sales personnel and field operations managers, which also focused on internet pharmacy diversion.[575]

As described, Cardinal's training efforts were defective in at least three regards. First, the training, like the rest of the controlled substances program at that time, was inappropriately limited to price diversion and internet pharmacies rather than being a holistic anti-diversion program for controlled substances. For example, in 2007 Know Your Customer training, Eric Brantley, Director of Quality and Regulatory Affairs, told participants that

[574] *See* Lakeland 2007 ISO at 2.

[575] *See* Special Committee Report at 11.

questionnaires were being used to look for red flags, which he defined as "[l]ooking for signs of Internet activity (shipping supplies, lack of walk-in customers, etc.) and filling prescriptions from questionable 'pain clinics'."[576] This is an artificially narrow, and inaccurate, rendition of the DEA's requirements pertaining to suspicious orders.

Second, before the training efforts described above, the Special Committee report did not reference any earlier substantial controlled substances training. This suggests that prior to 2006 Cardinal had no concerted training effort even though the CSA and the implementing regulations were in effect since 1971. A January 2005 Quality management meeting presentation provided confirmation on this point as the Enterprise Training Initiative section noted:

- There was a lack of corporate sponsorship for training;
- Training was left to the individual sites and was non-existent at some sites;
- There were no repercussions for not completing training or failing assessments; and
- There was both insufficient and redundant training.[577]

This lack of earlier training suggests that Cardinal's efforts in 2006-2007 appear to be more of an attempt by the company to demonstrate the existence of a controlled substances compliance program in the face of mounting enforcement pressures, rather than a genuine corporate effort to discharge its obligation to maintain an effective program to prevent diversion.

Third, the Special Committee specifically referenced that Cardinal developed two mandatory computer-based training courses but did not describe the content or note whether participants were required to pass an assessment to demonstrate comprehension of the information. While highlighting the number of courses given and the number of employees trained, as Cardinal does, are common compliance training metrics, they only are measures of activity rather than effectiveness. Therefore, the metrics cited by the Special Committee are useless in determining whether compliance training activities were effective.

10.5.5 Cardinal's SOM program modified in response to the DEA enforcement proceedings failed to meet the necessary standards in five key areas: threshold setting, threshold increases, due diligence, customer monitoring, and investigations.

As a result of the 2007 ISOs, Cardinal undertook a series of program modifications in order to reach the 2008 settlement agreement. These changes included adding additional headcount and adjusting the organizational structure, implementing new customer due diligence requirements, issuing new standard operating procedures, implementing an electronic monitoring system, and modifying how Cardinal set and utilized thresholds.[578] The Cardinal controlled substances program in this timeframe is defined largely by five SOPs:

[576] *See* E. Brantley presentation, *Know Your Customer Retail Pharmacy Questionnaire Training*, 12 (Oct. 2007), CAH_MDL_PRIORPROD_DEA07_02214751. ["KYC 2007 Training"]

[577] Operation One Cardinal Health Quality Management Meeting, Enterprise Training Initiative Quality/Regulatory, 30 (Jan. 13, 2005), CAH_MDL_PRIORPROD_DEA07_01181262 at CAH_MDL_PRIORPROD_DEA07_01181276.

[578] *See* Special Committee Report at 9-11.

- Process to Establish SOM Threshold Limits,[579]
- Sales-Anti-Diversion Alert Signals,[580]
- On-site Investigations,[581]
- Detecting and Reporting Suspicious Orders and Responding to Threshold Events and[582]
- Large Volume- Tactical and Analytical Committee Periodic Review Process.[583]

However, as discussed below, the program modifications undertaken did not result in an effective controlled substances compliance program. This occurred in part because the design and the actual SOPs were ambiguous, creating opportunity to circumvent the controls and because Cardinal personnel did not follow the established processes.

A. Establishing Thresholds

The December 2008 SOP entitled "Process to Establish SOM Threshold Limits" outlined how thresholds were set. The methodology defined in the SOP was complex and contained several sub-steps, but in general, to establish a threshold Cardinal would:

> (1) extract and formulate a list of customers that have purchased monitored items and historical sales data for those customers for all monitored items; (2) differentiate customers through segmentation by size and/or specialty; (3) evaluate historical controlled substance sales data per drug family, per month for each customer segment to establish appropriate threshold limits, using the multiples of 3, 5, or 8; (4) incorporate background information about the pharmacies to establish final threshold limits; and (5) apply rounding logic and finalize threshold limits.[584]

Cardinal told the House Committee that the new custom threshold limits were:

> designed to alert analysts automatically whenever a customer's order volume exceeded its assigned threshold. All orders that triggered threshold events were held and reviewed to determine whether the order was justified or was suspicious [and] [o]rders that were determined to be suspicious were not shipped.[585]

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[579] *See* Cardinal Health, Process to Establish SOM Threshold Limits, HSCSQRA-CAD-C-002 (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0004208. In 2010 as the result of a restructuring, this document was renumbered as PDQRA-CAD-C002 via Document Control Notice ("DCN") 2555 (CAH_MDL_PRIORPROD_AG_0000017).

[580] *See* Cardinal Health, Sales-Anti-Diversion Alert Signals, HSCSQRA-SAD-C003 (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0000323.

[581] *See* Cardinal Health, On-site Investigations, PDQRA-CAD-C008 (Nov. 5, 2009), CAH_MDL_PRIORPROD_DEA12_00014535 ["Investigations SOP"].

[582] *See* Cardinal Health, Detecting and Reporting Suspicious Orders and Responding to Threshold Events, PDQRA-CAD-C007 (Jan. 6, 2012), CAH_MDL_PRIORPROD_AG_0000154 ["Reporting SOs 2012 SOP"].

[583] *See* LV-TAC SOP 2012.

[584] *See* Special Committee Report at 12.

[585] *See* W.Va. Red Flags Report at 185.

The threshold formula, however, like the Ingredient Limit Report levels that preceded it, remains a mystery. For example, the threshold formula requires that once a monthly limit is determined from historical sales data, if the product is hydrocodone or oxycodone, the monthly limit is to be multiplied by a factor of 3.[586] The SOP presents no explanation or rationale for why hydrocodone or oxycodone monthly limits should be increased three-fold.[587] The Special Committee report suggests that the multiples were derived from DEA guidance "to chemical distributors approving the use of multiples of three and eight for drug products consisting of a listed chemical and a controlled substance."[588] However, the citation provided in the Committee report could not be verified as the webpage no longer exists.

However, thresholds could be increased by more than the factor of three. According to the SOP, Cardinal could apply a final set of additional upwards adjustments based upon background or Know Your Customer ("KYC") information.[589] The stated reason for this provision was to "adjust threshold limits based on the associated level of risk," such as increasing the threshold if the customer had "a documented diversion or loss prevention program."[590] This additional final adjustment, however, also provided Cardinal an opportunity to negate the algorithm and potentially make unsubstantiated and unregulated KYC adjustments resulting in threshold levels in excess of the system generated levels. Furthermore, the example provided in the SOP only requires a documented diversion or loss prevention program. Cardinal, therefore, was not required to ascertain whether the program worked in practice or was even being used. The net result of the KYC provision is that it creates a potentially significant "loophole" allowing Cardinal to adjust thresholds to satisfy customer needs regardless of the diversion potential.

In developing the new threshold methodology, Cardinal Health enlisted the help of several consultants, including:[591]

- **Deloitte**. Cardinal Health retained Deloitte at various times between 2007 and 2012. Part of Deloitte's work was to assist in a project management capacity with business and technology enhancements to Cardinal Health's Controlled Substance Anti-Diversion program.
- **Dendrite/Cegedim/Buzzeo PDMA**. BuzzeoPDMA and Dendrite were both acquired by Cegedim, which is now part of IQVIA (formerly IMSQuintiles). Cardinal Health engaged Dendrite in 2007 to consult on Cardinal Health's on-site investigations program and used Dendrite to assist with on-site pharmacy investigations. Cardinal Health continues to use investigators from Buzzeo/Cegedim to assist with on-site pharmacy investigations.

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586 *See* HSCSQRA-CAD-C002 at § 4.2.3(b)(vi).

587 It appears that the factor of 3 was derived from the Chemical Handler's Manual. Appendix E-3 entitled "Suspicious Order Reporting System for Use in Automated Tracking Systems." *See* Discussion *infra* at Section 5.3.2.

588 *See* Special Committee Report at 12, n. 9.

589 *See* HSCSQRA-CAD-C002 at § 4.2.4

590 *Id.*

591 *See* Cardinal Health, Inc., First Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests at 13-14, *In Re: National Prescription Opiate Litigation*, Master Docket No.1:17-MD-02804-DAP MDL No. 2804 (N.D. Ohio).

However, Cardinal Health appears not to have been fully transparent when describing how it used those consultants. For example, the SOP provides that "[i]n the event that an adequate sample does not exist to formulate a threshold limit for a Base Code, initial threshold limits established for the segment by **Deloitte** will be used as a baseline."[592] A January 2008 email from Carolyn McPherson, Director, Quality and Regulatory Affairs, was more explicit stating "Attached is [sic.] the thresholds by customer group list supplied by Deloitte."[593] Based on both the SOP and the email, Deloitte's role was more significant than simple project management as Deloitte apparently developed at least some threshold limits on behalf of Cardinal.

In the same vein, it appears that Cardinal engaged Dendrite/Cegedim/BuzzeoPDMA to do more than just assist with on-site pharmacy investigations, and instead they did a full-blown review of Cardinal's SOM system.[594] That engagement included "[a]n onsite review of Cardinal's suspicious order monitoring program/system including verification of the system's operational effectiveness, system integrity, and **regulatory suitability**."[595] This verification of regulatory suitability is not consistent with on-site pharmacy investigations.

What is most concerning is that while this type of misrepresentation or dissembling may be couched as a "litigation strategy," it speaks directly to Cardinal's culture and a lack of integrity; once more reinforcing the conclusion that Cardinal does not take its ethical and compliance obligations seriously.

B. Threshold Events

During this period Cardinal also implemented the Detecting and Reporting Suspicious Orders and Responding to Threshold Events SOP. Although ultimately retired in 2016,[596] the purpose of the SOP was to comply with or "exceed" distributor standards in CSA and DEA requirements.[597] The procedure also was intended to:

> provide guidance to Cardinal Health (CAH) employees in the Quality and Regulatory Affairs (QRA) section on responding detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about releasing or cutting orders that are suspicious or exceed a threshold.[598]

The procedure required QRA to review every order that was a held or cut (removal of the offending line items).[599] Held or cut orders were only deemed suspicious for DEA purposes if they meet at least one of three

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[592] *See* HSCSQRA-CAD-C-002 at § 4.2.3(c).

[593] *See* Email from Carolyn McPherson to S. Reardon, *et al.,* Deloitte Threshold Values By Type_Base_Size Combo-Report 2a.xls, 1 (Jan. 28, 2008), CAH_MDL_PRIORPROD_DEA07_00863981.

[594] *See* S. Reardon Deposition at 460:11-463:15 (Discussing Cegedim's work product and Reardon's role in it).

[595] *See* Email from Paul Hamby to J. Bennett, *et al.,* Cegedim Dendrite SOM review, 1 (December 15, 2007) (emphasis added) (Mr. Hamby was Cegedim's Director of Consulting and Validation Services.), CAH_MDL_PRIORPROD_DEA07_00869802.

[596] *See* Cardinal Health, Detecting and Reporting Suspicious Orders and Responding to Threshold Events, PDQRA-CAD-C007 (Oct. 17, 2016), CAH_MDL_PRIORPROD_AG_0001281 ["Reporting SOs 2016"].

[597] *See* Reporting SOs 2012. at § 1.2.

[598] *See* Reporting SOs 2012 at § 1.1.

[599] *Id.* at § 6.1.3

criteria: (a) order is of unusual size, (b) order is of unusual frequency, and (c) order deviates substantially from a normal pattern for the customer.[600]

Orders of unusual size were defined as those "**significantly larger** than orders normally placed by the customer or by **customers that have a size and type of business that is similar** to the ordering customer's business."[601] Orders of unusual frequency were defined as those "orders that occur **significantly more frequently** than the orders normally placed by the ordering customer or by **customers that have a size and type of business that is similar** to the ordering customer's business."[602] Orders that deviate substantially from the normal ordering pattern were defined as "orders that reflect a **significant deviation** from the customer's normal ordering pattern or that deviate substantially from the ordering patterns of **customers that have a size and type of business that is similar** to the ordering customers business."[603]

Cardinal's process however does not define "significantly larger," "significantly more frequently," or "significant deviation." Therefore, it is unclear what significant means in this context. The same situation existed with "customers that have a size and of business that is similar." Cardinal's process failed to outline how a similar customer was to be determined for purposes of comparison. However, in all three cases, the SOP just required QRA personnel to use available information and experience to make reportability determinations.[604]

The SOP also notes that unusual size errors might be unintentional (e.g., typographical errors or duplicate orders). The SOP also was unusually vehement requiring that:

> Unintentional order entry errors (including duplicate order entries) MUST NOT be reported as suspicious orders to DEA since the customer did not intend to place the order and MUST be cut with no changes to customer threshold and a readjustment of accrual to the level prior to the order entry error. (Emphasis in the original).[605]

Since reporting suspicious orders to the DEA did not guarantee regulatory action, it is highly usual for a company to worry about possible over-reporting. Furthermore, the emphasis suggests that Cardinal was looking for reasons not to report suspicious orders, which is reinforced by sudden removal of the language from the 2016 version of the SOP. Finally like the issues with the Alert Signals process, through the lack of precisely defined standards, Cardinal created a program that was susceptible to wide variation and being circumvented. Therefore, a claim that the program was an effective anti-diversion program is not supportable.

In another example of how Cardinal's program is convoluted and difficult to follow, Cardinal in 2012 implemented the Large Volume – Tactical and Analytical Committee ("LV-TAC") process which operated in

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[600] *Id.* at § 6.1.3(a-c).

[601] *Id.* at § 6.1.5 (emphasis added).

[602] *Id* at § 6.1.6 (emphasis added).

[603] *Id.* at § 6.1.7 (emphasis added).

[604] *Id.* at §§ 6.1.5.1, 6.1.6.1 and 6.1.7.1. These sections remained unchanged through the 2016 version. *See* Reporting SOs 2016 at §§ 6.1.5, 6.1.6 and 6.1.7.

[605] *Id.* at § 6.1.5.2.

parallel to the Detecting and Reporting Suspicious Orders and Responding to Threshold Events.[606] The LV-TAC was a committee comprised of the Senior Vice President QRA, Regulatory, Vice President of Supply Chain Integrity and Director of QRA Analytics, and VP of Sales or appropriate designee all of whom met "on a periodic basis (e.g., monthly)" to assess customers via a detailed review of "the top retail purchasers of commonly diverted controlled substances."[607]

It is not clear how Cardinal determined which customers were on the list. According to the SOP, "large purchasers of controlled substances" meant "[t]op retail purchasers of commonly diverted controlled substances," but could be generated "for the entire network" or "by distribution center and will include all CAH customers classified as 'Retail Pharmacies." Thus, when Cardinal defined the "top retail purchasers" it is unclear if that meant the top ten, top fifty or top one hundred. Furthermore, as with the other SOM procedures reviewed, Cardinal watered down the LV-TAC process in 2014 by eliminating the VP of Sales as a required committee member and removing the suggestion that periodic equaled monthly.[608] However, Cardinal also stripped out any reference to how the Committee's decisions go beyond the paper file and translate into action. The final step in the 2014 version of the process did not consist of notifying sales of the Committee's decision and taking some action as in the 2012 version, but rather required Cardinal to simply collect and file the data reviewed by Committee into the digital filing system.[609] Thus, by 2014, Cardinal seems to have eviscerated the Committee's authority.

C. New Pharmacy Questionnaire

Cardinal Health told the House E&C Committee that:

> In 2007, Cardinal Health began requiring completion of a New Pharmacy Questionnaire as part of the account approval process for all new retail independent pharmacies. The questionnaire collected general information about the pharmacy, its owner, and the pharmacist in charge; general information about the pharmacy's other suppliers; information about the pharmacy's customers and their primary method of payment for controlled and non-controlled substances; and the pharmacy's expected controlled substance ordering, among other information. Cardinal Health employees vetted these questionnaires and conducted an additional investigation where appropriate.[610]

As part of the 2008 settlement agreement, Cardinal agreed:

> [t]o the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing

[606] *See* LV-TAC SOP 2012.

[607] *Id.* at §§ 1.1 and 4.0.

[608] *See* Cardinal Health, Large Volume- Tactical and Analytical Committee Periodic Review Process, PRDQRA-CAD-C023, §§ 1.1 and 4.0 (May 29, 2014), CAH_MDL_PRIORPROD_CNTY_0000450.

[609] *See* LV-TAC SOP 2012 at § 7.0 *but compare* LV-TAC SOP 2014 at § 7.0.

[610] *See* W.Va. Red Flags Report at 115.

> patterns, and take appropriate action as required by this Agreement, DEA regulations, and other procedures established under Cardinal's compliance program.[611]

In the October 2007 training program about the new questionnaire, Mr. Brantley told participants that the Pharmacy Business Consultant was responsible for completing and submitting the questionnaire to Corporate Quality and Regulatory Affairs for approval after working with pharmacy owner.[612] He also made it clear that the Pharmacy Business Consultant was "the first line of defense for Cardinal in preventing diversion," and therefore, "[t]he questionnaire must be taken seriously and must be filled out thoroughly and completely."[613]

Despite the admonitions in the October 2007 training and the agreement with the DEA in 2008, the DEA in 2012 alleged that Cardinal failed to conduct meaningful due diligence on "its retail pharmacy chain customers."[614] Mr. Reardon in his deposition confirmed that Cardinal was relying on the chain customers to self-police and thus did not undertake independent due diligence using Cardinal employees.[615] Beginning in 2012, Cardinal changed its practices to stop relying simply on the chain store's internal due diligence.[616]

D. Anti-Diversion Alert Signals

At the same time Cardinal moved to individualized thresholds, the company also instituted new procedures to address customer monitoring and the handling of threshold excursions. In December 2008, Cardinal issued the "Sales – Anti-Diversion Alert Signals" SOP,[617] which was effective for only six months until it was completely rewritten "to conform to existing Cardinal Health practices."[618]

The purpose of the SOP was, as part of Cardinal's overall SOM program, to provide "process requirements for the continuous monitoring and reporting of customer order activities by Sales during the execution of the SOM program."[619] The SOP's focus was on "threshold event investigation activities."[620]

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[611] *See* 2008 CAH AMOA at 4.

[612] *See* KYC 2007 Training at 10.

[613] *Id.*

[614] *See* Letter from M. Leonhart, Order to Show Cause and Immediate Suspension of Registration, Lakeland, Florida Distribution Center, 3 (Feb. 2, 2012), CAH_MDL2804_02465982 at CAH_MDL2804_02465995 ["Lakeland 2 ISO"].

[615] *See* S. Reardon Deposition at 401:21-402:21.

[616] *See* Presentation by C. Morford, *2012 Annual Quality and Regulatory (QRA) Report to the Audit Committee of the Board of Directors,* 8 (Nov. 2, 2012), CAH_MDL2804_03262274 at CAH_MDL2804_03262440 ("Large Chain Customers – can't rely on controls of large, publicly traded chains; will conduct our own due diligence.").

[617] *See* Cardinal Health, Sales Anti-Diversion Alert Signals (Dec. 22, 2008), CAH_MDL_PRIORPROD_AG_0000323 ["Sales Alert SOP 2008"]

[618] *See* Cardinal Health, Sales Anti-Diversion Alert Signals, HSCSQRA-SAD-C003 at Change History (Jun. 9, 2009) (Document was changed by DCN-2423), CAH_MDL_PRIORPROD_AG_0000326 ["Sales Alert SOP 2009"}; *see also* Cardinal Health, Sales Anti-Diversion Alert Signals, HSCSQRA-SAD-C003, (May 1, 2013) (Showing the SOP as being retired as of that date), CAH_MDL_PRIORPROD_HOUSE_0000264.

[619] *See* Sales Alert SOP 2008 at § 1.0.

[620] *Id.*

According to the Alert Signals SOP, a "threshold event" was a situation where a customer's order was held because the "customer's accrual for a drug family in a given month surpasses the assigned threshold limit."[621] According to the SOP, once the threshold event is triggered, the order is held "pending regulatory review."[622]

The definition of "held order" was significantly changed between the 2008 and 2009 SOP versions regarding the treatment of subsequent orders and the handling of notifications. In the 2008 version, subsequent orders by the customer in the same drug family would be held "unless the threshold is increased by QRA, or unless the accrual is reset to zero at the beginning of the month."[623] The 2009 version simply provided that subsequent orders would be held "as a continuation of the original event."[624] Despite DCN-2423's rationale for the change, this difference in wording appears to be one to remove potentially problematic wording rather than a change in practice. The 2009 version does not prevent QRA from increasing thresholds nor does it clearly address what happens when the monthly accrual resets.

In the case of notifications, the 2008 version made no mention of whether the customer or Cardinal sales would be informed of the threshold event, with the presumption being that both received notice.[625] The 2009 version specifically provided that while sales will not receive a notification of the hold order, the customer will see on the invoice "'held pending regulatory review.'"[626] The 2009 version does not preclude the sales team from receiving notice of held orders, only that the notice would not be system-generated. In the case of the customer, the notice of the hold would allow them to determine with some precision their thresholds, because they would know how much was dispensed when the held order was placed. Therefore, Cardinal was in effect giving customers the ability to circumvent the threshold control by manipulating order timing, requesting prospective threshold increases, etc. The subtlety with the Cardinal system was that Cardinal's system undercut itself, thereby insulating the sales team from the appearance of directly subverting the threshold control.

The remainder of the procedure is devoted to detailing how sales personnel are to conduct "an inspection that looks for the Anti-diversion alert signals."[627] When conducting the inspection, the salesperson was to complete an online survey if the customer exhibited two or more of the alert signals to start the QRA Anti-Diversion team review process.[628] If no signs of diversion were noted, then the sales representative completes the inspection and the form.[629] However, the SOP is not explicit on when inspection and completion of the online survey is required. The SOP does contain an attachment with a memo to the Retail Independent Sales Professional

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[621] *Id.* at § 4.1.

[622] *Id.* § 4.1 (Definition of "held order").

[623] *See* Sales Alert SOP 2008 at § 4.1 (Definition of "held order").

[624] Sales Alert SOP 2009. § 4.1 (Definition of "held order").

[625] *See* Sales Alert SOP 2008 at § 4.1 (Definition of "held order").

[626] Sales Alert SOP 2009 at § 4.1 (Definition of "held order").

[627] Sales Alert SOP 2008 at § 4.2 (Procedures for Reporting).

[628] Sales Alert SOP 2008 at § 4.2(2) and (3).

[629] *Id.*

describing "*The Highlight Report,"* which is the unofficial name.[630] It shows the current monthly purchases of controlled substances as compared to a three-month rolling average of controlled substances sales. Customers are then flagged based upon the percentage increase in sales. There are three tiers: Watch List (5% or at least a $2,500 increase), Yellow Flag (10% or at least a $5,000 increase), and Red Flag (15% or at least a $10,000 increase). Only Red Flag customers required an immediate store visit. Any customer that falls in the Watch List or Yellow Flag categories for three consecutive months was escalated to Red Flag status.

On a first pass, the Alert Signals inspection process looks adequate on paper. A closer inspection, however, reveals that in actuality, the process is filled with "loopholes" that allowed Cardinal to claim the company engaged in close customer monitoring without doing it. This is supported by Chris Lanctot's, Vice President of Sales for the Central Region, stated belief that sales did not have a role in ensuring compliance with the requirements the CSA, but simply complied with the directions provided by the QRA department.[631]

First, the primary difference between the 2008 and 2009 versions can be seen in the list of "Anti-diversion alert signals" with the 2009 version being much more expansive and covering ambulatory surgical centers, and physicians' offices, as well as pharmacies.[632] Conspicuously missing, however, from either version are pain management and other clinics; areas where significant diversionary activity already was occurring.

Second, regardless of its stated purpose, the Highlight Report process was a notification mechanism, alerting sales representatives to which customers were attracting attention through their purchasing patterns of controlled substances. The Highlight Report process did not require any action until the customers hit Red Flag status. Therefore, the astute sales representative could work with customers to either increase the thresholds or rework the ordering patterns such that the flag did not trip. Furthermore, Watch List or Yellow Flag customers only reached Red Flag status after three consecutive months. By adjusting ordering patterns, a customer could permanently avoid being on either list by simply adjusting hitting the Watch List or Yellow Flag for two months in a row with an intervening "normal" third month, which would reset the three-month trigger again.

Third, the Highlight Report compares the current month to a three-month rolling average of controlled substances sales, but it is unclear what makes up "controlled substances sales." If Cardinal included all controlled substances sales across all customers, including chain stores, then the average would be so high as to render it meaningless for smaller independent retail pharmacies which appear to be the target of this process.

Fourth, despite the 2009 change from being directed to all Sales Professionals versus Retail Independent Sales Professionals in the Highlight Report memorandum, the system still does not appear to apply to chain store pharmacies.[633] If it did, the sales increase limits are set so low that large chain customers such as Giant Eagle, CVS and Walgreens would need site visits on a monthly basis. Therefore, it appears that the change in addresses was done to avoid potentially difficult questions from a regulatory inspector or external auditors, about the limited application of the program. It is an important distinction that the Special Committee Report

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[630] *See* Sales Alert SOP 2008 at Attachment 1 (A memo dated 12/05/2008 from Tom DeGemmis, SVP to the Retail Independent Sales Professionals). The 2009 version contains virtually the same memo but addressed to "Sales Professionals" and dated 5/11/2009. *See* Sales Alert SOP 2009 at Attachment 1.

[631] *See* S. Lanctot Deposition at 46:5-18 (Oct. 10, 2018).

[632] Sales Alert SOP 2009 at § 4.2.1 (Alert signals).

[633] Sales Alert SOP 2008 at Attachment 1; *but cf.* Sales Alert SOP 2009 at Attachment 1.

seems to gloss over.[634] In toto, as a diversion prevention control, the Alert Signal process is so easily circumvented that it cannot be considered much of a control at all.

E. On-site Investigations

Investigating potentially suspicious orders is a key component of any SOM program. Cardinal, however, did not establish a formal documented process for investigations until 2008.[635] The SOP was intended to "provide guidance to CAH employees by outlining the steps involved in the conduct of on-site investigations of Cardinal Health's customers to obtain information regarding their potential risk for diversion of regulated drugs."[636] This process begins when "[a] pharmacist evaluates each threshold event according to established procedures and documents a request for an onsite investigation by changing the status of the event in the SOM system to 'Site Visit.'"[637] Presumably, this is a reference to the Detecting and Reporting Suspicious Orders and Responding to Threshold Events procedure, but the Investigations SOP fails to make a clear linkage.

The SOP also notes that the "Inspectors have no authority to require compliance with any request" for information.[638] Given that Cardinal entered into purchasing contracts with customers, a normal compliance provision involves the inclusion of a "right to audit clause." These clauses give a party the right to obtain documentation and conduct interviews. Without such authority, on-site investigators faced a substantial hurdle to obtaining the necessary information.

Finally, the investigative resolution process is not clear. Once the report was completed and the Director rendered a final recommendation, the next step was:

- A decision to continue the sale of regulated drugs to the customer requires and evaluation of the customer's threshold limits for regulated drugs and adjustments when supported by findings documented in the case. The Director, or another pharmacist, shall conduct such an evaluation and adjust thresholds appropriately.
- A decision to discontinue the sale of regulated drugs to the customer requires the termination of the customer from the Cardinal Health system and notification to state and federal regulatory bodies.[639]

What is not clear is how the decisions are implemented. For example, the Director clearly is not the person managing the termination, but the SOP is silent on who outside of QRA receives notice. Thus, as written the SOP is a dead-end process that results in the creation of a file but no apparent real action.

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[634] *See* Special Committee Report at 13.

[635] *See* Cardinal Heatlh, On-site Investigations, PDQRA-CAD-C008 (Nov. 5, 2009) (Initial issue of the procedure was 12/22/2008) CAH_MDL_PRIORPROD_DEA12_00014535. ["On-site Investigations SOP's].

[636] *Id.* at § 1.1.

[637] *Id.* at § 4.2.1.

[638] *Id.*at § 4.3.5.

[639] *Id.* at § 4.4.3.

F. QRA SOM Customer Analytics General Work Instructions

In January 2013, Cardinal developed a set of general work instructions covering SOM Customer Analytics.[640] Typically, Work Instructions are a type control document issued as a supplement to the more formal policies and procedures and are intended to provide additional guidance to employees on how to implement specific policies and procedures.[641] As Todd Cameron noted, this particular set of Work Instructions provided "action-oriented details" in addition to what was set out in Cardinal's existing set of SOM policies and procedures.[642] However, the General Work Instructions are not referenced in Cardinal's standard operating procedure on detecting and reporting suspicious orders.[643]

These General Work Instructions outlined "the assessment and adjustment process" from beginning to end.[644] As described, "[t]he initiation of an assessment could result from an early dialogue notice, held order, or proactive communication from the customer or sales department. The assessment could conclude with no change of a threshold limit, an increase or decrease of a threshold limit, resolution of a held order, and/or the report of a suspicious order to DEA."[645]

The General Work Instructions also outline "the sequence of steps and corresponding decisions that should generally occur for each type of assessment."[646] These steps included:

- Determining the assessment was warranted;[647]
- Assessing a customer's objective criteria;[648]
- Conducting an empirical review to "assess the reasonableness of the information and underlying basis for the threshold limit increase; and"[649]
- Determining eligibility for the increase based on the objective criteria and empirical review.[650]

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[640] *See generally* Cardinal Health, *QRA SOM Customer Analytics General Work Instructions*, (Sept. 20, 2013) (This is a revised version of the work instructions originally effective on January 15, 2013), CAH_MDL2804_00012249 ["SOM Analytics WI"].

[641] Work Instructions are a format that typically is employed in a manufacturing setting. In the manufacturing setting, Work Instructions usually are developed, revised and approved using the standard document control processes applicable to policies and procedures. *See generally* Appendix B, Figure 1 *infra*. However, here it seems that Cardinal considered the General Work Instructions to be "working guidelines." *See* Email from K. Howenstein to K. Anna-Soisson, FW: assistance, (Apr. 28, 2014), CAH_MDL2804_00012244.

[642] *See* State of Montana, Office of the Attorney General, Office of Consumer Protection Deposition of Todd Cameron, 118:2-119:5, (Sept. 26, 2018).

[643] *See* Cardinal Health Standard Operating Procedure Pharmaceutical Distribution, Detecting and Reporting Suspicious Orders and Responding to Threshold Events, PDQ-CAD-C007 (Jul. 18, 2014), CAH_MDL2804_000122245. For example, the General Work Instructions are not listed in the SOP's references and related documents section although another SOP (PDQRA-CAD-C008) is listed.

[644] *See* SOM Analytics WI at 1.

[645] *Id.*

[646] *Id.*

[647] *See id.* at 2-4

[648] *See id.* at 5-6.

[649] *Id.* at 6.

Although the objective and empirical criteria are detailed and appear robust on their face, the Work Instructions provided a substantial "loophole" that allowed Cardinal to ignore situations where "the customer fails the objective criteria, and after empirical review, there is no justification for the threshold adjust[ment]."[651]

According to the Work Instructions, "[c]ustomers may receive a specified percentage of dosage units over their thresholds, [redacted][4] Therefore, despite making modifications to the SOM program after its 2012 DEA settlement, Cardinal persisted in maintaining practices that served to undercut those modified controls and gave the company the ability to apply its anti-diversion controls on a discretionary basis as demonstrated by these General Work Instructions.

In April 2014, Ullrich Mayeski, Cardinal's Director of Investigations in Quality and Regulatory Affairs, asked Kim Howenstein and Kimberly Anna-Soisson to develop a presentation for Mr. Mayeski to give to Cardinal's Compliance Officers at the distribution centers that they could "share with the DEA on-site and walk through with them during the inspection" to address "basic [SOM] components, particularly what happens when a threshold hits and cutting/reporting."[655] However, the June 2018 version of that presentation does not mention the ability to approve additional dosage units over the allotted thresholds found in the Working Instructions, except in the speaker's note section.[656]

In an email to Ms. Howenstein, Ms. Anna-Soisson, Regulatory Management Manager for Cardinal, stated she "intentionally left out the part about releasing beyond the TH [threshold]," because she "did not want to draw attention to the practice but agree that the CO's should know it exists."[657] Ms. Anna-Soisson went on to add that she wondered "if we should take out any reference to the working guidelines since we don't produce those."[658]

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650 *Id.* at 9.

651 *See id.* at 5, § 4.a.c.i.

652 *See id.* 7, § 4.a.c.i.vi.

653 *See id.* at 15 (Appendix 5, Table 5: Customer Release Percentage); *see also* Appendix D, Figure 2 *infra* (showing the actual table).

654 *See id.* 7, § 4.a.c.i.vi.

655 *See* Email from U. Mayseki to K. Anna-Soisson and K. Howenstein, assistance, (Apr. 28, 2014), CAH_MDL2804_00012244.

656 *See* Cardinal Health Quality & Regulatory, Cardinal Health Suspicious Order Monitor (SOM): Program Overview, 6 (Jun. 2018), CAH_MDL2804_00012954.

657 *See* Email from K. Howenstein to K. Anna-Soisson, RE: Adjustments made can you take a quick look, (May 1, 2014) (Ms. Howenstein's email contains a copy of the text of Ms. Anna-Soisson's original message.), CAH_MDL2804_00012953.

658 *Id.*

Since the General Work Instructions are written standards governing how Cardinal's SOM program operated and by the documents own words, applied to "all individuals who have the ability and/or direct responsibility for assessing and adjusting customer threshold limits,"[659] it is concerning that Cardinal did not specifically reference them in the SOM SOPs and apparently had a policy not to disclose them. Regardless of the intent behind these actions, Cardinal, by making no reference to these General Work Instructions was maintaining a *sub rosa* process that failed to meet the standards of an effective compliance program.

10.6 Accountability - Consistent Enforcement

10.6.1 Cardinal does not enforce the standards of the program, and thus there is no real accountability for the program's lack of effectiveness.

While Cardinal "removed" certain staff members from positions of authority for controlled substances compliances, these staff members were simply transferred to other parts of the organization and thus never held accountable for their roles in the program's failure:

1. **Stephen Reardon** – Mr. Reardon, who oversaw the SOM program prior to 2007 was removed from controlled substances compliance responsibilities in 2007 when Michael Moné took over. However, he was shifted into a Vice President of Regulatory Operations where he remained until leaving Cardinal in 2016.
2. **Michael Moné -** Mr. Moné was involved with the anti-diversion team until 2012. He was replaced because "evaluation[s] of customers and orders had been heavily focused on the clinical expertise and subjective judgment of the pharmacists in the anti-diversion group."[660] However, he was transferred to Cardinal's law department where he continues to service Cardinal as Vice President and Associate General Counsel.[661]
3. **Steve Morse –** Mr. Morse was the Director of Supply Chain Integrity until he was removed in 2012 to become Quality and Regulatory Manager under Stephen Reardon in Regulatory Operations. He was transferred because he was "not as strategic as his former position required and there were questions about his judgment."[662] However, his new role requires "good judgment" as a requirement of the job.
4. **Gilberto Quintero –** Mr. Quintero was Senior Vice President of Quality and Regulatory Affairs from 2009 to 2015.[663] In 2015, he was promoted to Chief Quality and Regulatory Affairs Officer – Pharmaceuticals & Medical Devices.[664]

Cardinal hired Craig Morford in 2008 to be its Chief Compliance Officer "with a mandate to establish a premier anti-diversion system."[665] Mr. Morford remains Cardinal's CCO, as well as being its Chief Legal Officer;

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[659] *See* SOM Analytics WI at 1.

[660] *See* Special Committee Report at 34-35.

[661] *See* Organization Chart 2012-2015, P1.4592.

[662] *See* Special Committee Report at 34-35.

[663] *Id.*

[664] *See* Gilberto Quintero LinkedIn Profile, https://www.linkedin.com/in/gilbertoquintero/ (last accessed Jan. 29, 2019).

however despite having failed in his mandate to establish the premier anti-diversion and being the senior most officer responsible for controlled substances compliance, Cardinal has failed to hold him accountable.

By failing to hold these individuals accountable for the controlled substances program's established lack of effectiveness, Cardinal's compliance program is merely words on paper that do not meet the statutory and regulatory requirements.

11 AmerisourceBergen Corporation

11.1 Background

AmerisourceBergen Corporation ("AmerisourceBergen" or "ABC") traces its origin back to 1871 and the founding of the Brunswick Drug Company.[666] Through a series of mergers and acquisitions beginning with the Bergen Drug Company in 1969, the Amerisource Health Corporation in 2001, and finally H.D. Smith in January 2018, AmerisourceBergen has become a worldwide distributor with more than 20,000 employees.[667] Ranked 12th on the Fortune 500 with revenues in excess of $150 billion,[668] ABC declares that:

> We provide the pharmaceutical products and business solutions that improve access to care. We operate the backbone of the healthcare supply chain.[669]

ABC distributes controlled substances through two wholly owned subsidiaries, AmerisourceBergen Drug Corporation ("ABDC") and AmerisourceBergen Specialty Group ("ABSG"), with ABDC being dominant.[670]

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[665] *See* Special Committee Report at 9.

[666] *See* AMERISOURCEBERGEN, *Our History* at https://www.amerisourcebergen.com/abcnew/about-our-history (last accessed Jan. 19, 2019).

[667] *Id.*; *see also* AMERISOURCEBERGEN, *Who We Are* at https://www.amerisourcebergen.com/abcnew/about-who-we-are (last accessed Jan. 19, 2019); *see also* BUSINESSWIRE, AmerisourceBergen Completes Acquisition of H.D. Smith, (Jan. 3, 2018, 0800 EST) (At the time, H.D. Smith was the largest independent wholesaler in the U.S.) at https://www.businesswire.com/news/home/20180103005161/en/AmerisourceBergen-Completes-Acquisition-H.-D.-Smith.

[668] FORTUNE 500, *Amerisource Bergen* (last accessed Jan. 21, 2019), http://fortune.com/fortune500/amerisourcebergen/.

[669] *See* AMERISOURCEBERGEN, *Who We Are* at https://www.amerisourcebergen.com/abcnew/about-who-we-are (last accessed Jan. 19, 2019).

[670] As used in this report, AmerisourceBergen or ABC includes two subsidiaries that distribute controlled substances. The first, AmerisourceBergen Drug Corporation or ABDC, "distributes pharmaceuticals products, equipment, and systems … [and] serves healthcare providers, independent retailers, and pharmacies." *See* Company Overview of AmerisourceBergen Drug Corporation, BLOOMBERG at https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=928736 (last accessed Jan. 21, 2019 3:50 PM ET). AmerisourceBergen Specialty Group "distributes medical products to healthcare providers … [including] chemotherapy and supportive care products to oncology practices." *See* Company Overview of AmerisourceBergen Specialty Group, BLOOMBERG at https://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=27144580 (last accessed Jan. 25, 2019 9:12 AM ET).

Although prescription opioids account for less than 2% ($3 billion) of ABC's total revenues, [671] this translates into a vast number of dosage units.

ABC's controlled substances program traces its origins back to Bergen Brunswig's system. At the formation of AmerisourceBergen in 2001, ABC adopted the Bergen Brunswig anti-diversion system.[672] During the review period, ABC, and its predecessor Bergen Brunswig have made periodic updates to its controlled substances program with the major milestones being 1997, 2007 and 2014.[673]

On the enforcement front, AmerisourceBergen Drug Corporation entered into a settlement with the DEA in June 2007 to resolve allegations that the company failed to maintain effective controls against diversion.[674] As noted in ABC's press release announcing the settlement, "[t]he agreement requires the Company to implement an enhanced and more sophisticated order monitoring program in all AmerisourceBergen Drug Corporation distribution centers by June 30, 2007, after which the Company must pass several DEA inspections of the new program for the reinstatement to become effective [in August 2007]."[675]

Although the company has not been the subject of a second enforcement action by the DEA, ABC has undergone several subsequent DEA inspections that have noted deficiencies in ABC's recordkeeping processes.[676] Furthermore, ABC has been embroiled in other serious compliance breaches, with the most notable being the 2018 anti-kickback settlement involving ABSG.[677]

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[671] Written Statement of Steven H. Collis Chairman, President, and Chief Executive Officer AmerisourceBergen Corporation Before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives at (May 8, 2018), https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-Wstate-CollisS-20180508.pdf ["Collis Statement"].

[672] *See* Email from C. Zimmerman to P. Ross, Emailing BOD CS TPs 8.10.17 (8.6.17) Final, 2 (Aug. 7, 2017), ABDCMDL00273269 -ABDCMDL00273270 ["BOD Talking Points"].

[673] *See* BOD Talking Points at 2.

[674] *See* Settlement and Release Agreement between the U.S. Department of Justice, Drug Enforcement Administration and AmerisourceBergen Drug Corporation (Jun. 22, 2007), ABDCMDL00279854 ["ABDC Settlement"].

[675] Amerisource Bergen Corporate Press Release, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of Its Orlando Distribution Center's Suspended License to Distribute Controlled Substances* (Jun. 22, 2017), http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its.

[676] *See* Email from Steve Mays to D. May and C. Zimmerman, *FW: DEA Audit Tracking* (May 16, 2017), ABDCMDL00253868.

[677] In September 2018, ABC and AmerisourceBergen Specialty Group ("ABSG") agreed to pay $625 million and entered into a five-year Corporate Integrity Agreement ("CIA") to settle allegations of distributing misbranded oncology products and harvest[ing] "overfill" from the original vials of [chemotherapy] drugs … [t]hat enabled the company to create more doses than it bought and generate at least $99.6 million of extra profit. … AmerisourceBergen was also accused of billing multiple doctors for individual vials, causing them to bill the government more than once, and paying kickbacks to induce doctors to buy drugs through the pre-filled syringe program." *See* Jonathan Stempel, *AmerisourceBergen to pay $625 million in U.S. civil fraud settlement*, REUTERS (Oct. 1, 2018, 2:16 PM), https://www.reuters.com/article/us-amerisourcebergn-settlement/amerisourcebergen-to-pay-625-million-in-u-s-civil-fraud-settlement-idUSKCN1MB3IT.

11.2 Executive Summary

In contrast to both McKesson and Cardinal Health, AmerisourceBergen's culture is a paradox with the company presenting a different "public" and a "private" face. Understanding this paradox is central to understanding ABC's approach to controlled substances compliance.

Publicly, AmerisourceBergen maintains and apparently believes that ABC's controlled substances compliance program always was compliant. ABC further maintains that any changes made to the program, including those resulting from the 2007 settlement, were the result of ABC's cooperative working arrangement with the DEA, not a compliance breach.

Privately, ABC, and those responsible for the controlled substances program, not only were conversant with the DEA's expectations for distributors, but they worked to configure a program that only addressed the bare minimums and did not interfere with ABC's pursuit of ever-increasing revenues. Moreover, internally, ABC attempts to shift its responsibilities to maintain effective anti-diversion controls to the DEA, based on a lack of direct communication by the DEA to ABC. Thus, ABC's poor compliance culture substantially contributed to it ineffectually addressing its obligations as a distributor of controlled substances.

Expanding on that notion of dialog with the DEA, AmerisourceBergen developed the misguided narrative that it was entitled to regular communications with the DEA, including having the DEA supply it with information on diversionary customers and review its systems. Despite receiving contrary information directly from the DEA, this expectation persisted, and it simply ignores the reality that the responsibility to identify and report suspicious orders as well as maintain an effective anti-diversion program rests with the distributor and not the DEA.

Also, in contrast to both McKesson and Cardinal Health, AmerisourceBergen, beginning in 2007, applied and continues to apply effort and resources towards improving its controlled substances compliance program. Unfortunately, however, most of ABC's efforts dedicated to controlled substances compliance have been misapplied and thus ineffective at achieving a credible and workable anti-diversion program.

Poor program design and inconsistent application of the standards that were developed exacerbated the deficiencies in AmerisourceBergen's controlled substances program leading to a predictable outcome that ABC's program credibly failed to identify, report and stop suspicious orders.

11.3 Impact

An example of the failure to maintain a credible anti-diversion program can be seen in West Virginia. As the House Energy and Commerce Committee uncovered, between 2005 and 2016, AmerisourceBergen distributed 248.16 million dosage units of hydrocodone and oxycodone to West Virginia customers.[678] During the same period, ABC reported a total of 2013 suspicious orders.[679] Assuming that 2013 suspicious orders are the accurate universe of suspicious orders out of 248.16 million dosage units shipped, then, on average, ABC

[678] *See* U.S. House Energy & Commerce Committee Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, 115th Cong., 6 (Dec. 19, 2018), P1.2060 ["W.Va. Red Flags Report"].

[679] *See* Appendix E, Figure 3.

should have filed approximately 183 reports per year. However, the number of suspicious orders ABC submitted to the DEA and blocked from shipment fluctuated widely from 6 in 2007 to a peak of 792 in 2013 and back to 3 in 2016. This wide variability is indicative of an unstable and dysfunctional program, and certainly one that fails the effectiveness test.

A similar fluctuation can also be seen in Ohio's Summit and Cuyahoga Counties. For Summit County, ABC's reports to the DEA fluctuated from 0 suspicious orders from 2007 to 2009 to a high of 13 orders in 2012 and back to 0 reported from 2014 to 2018.[680] In the case of Cuyahoga County, the fluctuation is even more dramatic. ABC's reports to the DEA in that county went from 0 suspicious orders to a high of 155 in 2013 back to 0 in 2016-2018.[681]

Below are just a few examples illustrating how ABC's approach to its anti-diversion program translated into various retail pharmacy stores obtaining high levels of opioids with little or no investigation or interrogation.

Clark Lowcost Pharmacy

Clark Lowcost Pharmacy was a pharmacy in Cuyahoga County, Ohio. In October 2010, ABC completed a threshold review request form to reflect that the pharmacy was purchasing more than $120,000 total dollar volume per month.[682] Ron Kline, Clark's Account Manager, provided three reasons for the request:

1. The account was "within several miles" of two hospitals, one of which had a pain clinic.
2. Clark was close to the Westshore Family practice, which has a pain clinic.
3. "With the old Oxy soon to be off the market they have been buying the Unit Dose on the old. In doing this they are picking up new business (beyond just the oxy)." [683]

As a result, despite multiple "red flags", Clark's customer size designation went from "small' to 'medium" on October 25, 2010 and was later increased once more in January 22, 2012 from "medium" to "large."[684]

Review of Clark Lowcost Pharmacy Threshold Increases (July 2010 to December 2011)[685]

Date of Threshold Increase	Customer Size Designation	Max. Threshold Allotment	Actual Threshold Amount Approved	% Over Default Threshold
July 16, 2010	Small	[redacted]	[redacted]	53.64%
July 20, 2010	Small			61.73%
October 19, 2010	Small			100%
October 25, 2010	**Customer Size Changed from "[redacted] Medium"**			

[680] *See* Appendix E, Figure 4.

[681] *Id.* at Appendix E, Figure 4.

[682] *See* Amerisource Bergen, Request for Threshold Review, (Oct. 18, 2010) (submitted by Ron Kline, Clark's Account Manager), ABDCMDL00158730.

[683] *Id.*

[684] *See* CSRA Comment Report Request for All Opioid Items from Cuyahoga County, Ohio, ABDCMDL00279842.

[685] *See* AmerisourceBergen, Legacy Threshold Override Report for Multiple Customers of Ohio from 01/01/2007 to 12/31/2012, (undated), ABDCMDL00279831; *see infra* Appendix E, Figure 1.

February 4, 2011	Medium	[redacted]	[redacted]	21.30%
December 29, 2011	Medium	[redacted]	[redacted]	150%
January 22, 2012	**Customer Size Changed from "Medium to Large"**			

As the table of Clark's threshold increases from July 2010 to December 2011 illustrates, ABC arbitrarily changed the customer size designation to adjust for the fact that ABC systematically ignored the size designation criteria and allowed Clark to order excessive quantities of the solid oxycodone formulation that should have triggered a suspicious order report for Clark.[686] The net effect of the customer size changes was to first double (from [redacted]o [redacted]), and then more than triple (from [redacted] to [redacted]) the number of monthly oxycodone solid dosage units that that Clark Lowcost Pharmacy could order from ABC.[687]

In addition, the threshold increase granted in December 2011 was granted until 2039 (a full 28 years).[688] However, even with this excessive threshold level, ABC continued to allow Clark to ignore ABC's threshold requirements, resulting in the pharmacy appearing five times on ABC's OMP Above Parameter Report for Ohio from January 2013 to December 2017.[689]

Church Square Pharmacy

Church Square Pharmacy also was in Cuyahoga County, under the same ownership as Clark Lowcost Pharmacy.[690] In November 2011, Ron Kline completed a threshold review form noting:

> This account was primary with us doing close to and a little over $300,000/month. Then they started to use HD Smith as a primary due to cost of goods and the volume dropped to below $100,000/month. After better understanding our cost of goods factoring in rebates they are now going to use us as a primary. Can their store classification of a medium be reevaluated at this time?[691]

From November 2011 to April 2012, Church Square total monthly sales volume increases from below $100,000 per month to $500,000 per month.[692]

Review of Church Square Pharmacy Threshold Increases (July 2010 to December 2011)[693]

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[686] *See infra* Appendix E, Figure 1.

[687] *See infra* Appendix E, Figure 1.

[688] *See* AmerisourceBergen, Legacy Threshold Override Report for Multiple Customers of Ohio from 01/01/2007 to 12/31/2012, (undated), ABDCMDL00279831.

[689] *See* AmerisourceBergen, *OMP Above Parameter Report for Ohio: January 2013 to December 2017*, (undated), ABDCMDL00045074; *see infra* Appendix E, Figure 1.

[690] *See* Email from D. Stertzbach to V. McDaniel, *et al.*, McKesson Pharmacy Systems, (Mar. 25, 2011), ABCMDL00158372.

[691] Amerisource Bergen, Request for Threshold Review, (Nov. 19, 2011), ABDCMDL00158675.

[692] *Id.*; Amerisource Bergen, Request for Threshold Review, (Apr. 27, 2011), ABDCMDL00158734.

[693] *See* AmerisourceBergen, Legacy Threshold Override Report for Multiple Customers of Ohio from 01/01/2007 to 12/31/2012, (undated), ABDCMDL00279831; *see infra* Appendix E, Figure 1.

Date of Threshold Increase	Customer Size Designation	Max. Threshold Allotment	Actual Threshold Amount Approved	% Over Default Threshold
November 22, 2010	**Customer Size Changed from "Medium to Large""**			
January 21, 2011	Large	[redacted]	[redacted]	13.47%
May 31, 2011	Large	[redacted]	[redacted]	32.34%

Like Clark, AmerisourceBergen adjusted Church Square's customer size designation from "small' to "medium" on September 21, 2009 and from "medium" to "large" on November 22, 2010. [694] Once again, AmerisourceBergen allowed Church Square to exceed its maximum threshold allotment for the solid dosage form of oxycodone even though the pharmacy already was considered "large," and the second time, the threshold increase was granted in May 2011, it was granted until 2039 (28 years).[695] The pattern of exceeding established thresholds continued as Church Pharmacy appeared five times on ABC's OMP Above Parameter Report for Ohio from January 2013 to December 2017.[696]

11.4 Company Commitment – Compliance Culture, Organization & Resources

11.4.1 The "private" versus "public" cultural paradox within AmerisourceBergen hampered its ability to create and maintain an effective controlled substances compliance program.

AmerisourceBergen's culture throughout the period is characterized by a public versus private paradox. Thus, there are two faces to AmerisourceBergen: a "public" and a "private" face. Publicly, ABC acknowledges that distributors have a role in preventing diversion under the Controlled Substances Act. AmerisourceBergen also states publicly that it takes this role seriously and maintains that its controlled substances program is compliant even though it has changed and updated its program during the period. ABC continues to maintain that stance in the face of evidence about the program's deficiencies documented and provided to it by outside parties (e.g., the DEA and FTI).[697]

In public, ABC's current Chairman, President, and CEO, Steven Collis in hearings before House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, acknowledged that with respect to opioids, ABC's "distribution role in the [drug supply] system is vital, yet limited, " but that the company is "responsible for getting those medicines to tens of thousands of sites of care every day, including pharmacies, hospitals, and clinics, which administer or dispense the medicines on prescriptions written by licensed health

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[694] *See* CSRA Comment Report Request for All Opioid Items from Cuyahoga County, Ohio, ABDCMDL00279842.

[695] *See* AmerisourceBergen, Legacy Threshold Override Report for Multiple Customers of Ohio from 01/01/2007 to 12/31/2012, (undated), ABDCMDL00279831. ABC also granted thresholds with 2039 expiration dates to Euclid Family Pharmacy (Cuyahoga County) and Ritzman Pharmacy #106 (Summit County). *Id.*

[696] *See* AmerisourceBergen, *OMP Above Parameter Report for Ohio: January 2013 to December 2017*, (undated), ABDCMDL00045074; *see infra* Appendix E, Figure 1.

[697] *See, e.g.*, Email from Steve Mays to D. May and C. Zimmerman, FW: DEA Audit Tracking (May 16, 2017), ABDCMDL00253868; FTI Consulting, Inc., Health Solutions Practice, *AmerisourceBergen Corporation CSRA Process Review, Phase 1 Narrative Report*, 3 (Aug. 25, 2015), ABDCMDL00274105 ["FTI Narrative"]

care providers."[698] AmerisourceBergen contends that the company "worked with the DEA to enhance the system in 1998, and again in 2007, and have continually reviewed and improved it [the anti-diversion program], including a comprehensive 2015 revision to build on current data, respond to trends in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools."[699] This is the public face of AmerisourceBergen.

The public face of AmerisourceBergen also contends that its controlled substances compliance program always was compliant. For example, Chris Zimmerman, Senior Vice President Corporate Security and Regulatory Affairs and Chief Compliance Officer,[700] in his deposition framed the DEA communications with the company, including during the 2007 settlement, as AmerisourceBergen simply was being asked to modify its program, as opposed to the fact that DEA was notifying ABC its program was operating contrary to DEA requirements.[701]

On the private side, there was the expectation that ABC was entitled to get regular guidance from the DEA. For example, in his 2017 Board talking points, Mr. Zimmerman referenced the fact that ABC enhanced its controlled substances program "without participation or input from the DEA, as DEA had stopped communicating with industry at this point."[702] However, the DEA was not obligated to participate in or provide input on ABC's program, and doing so would have run contrary to the DEA's longstanding position that it does not endorse particular systems or programs. Furthermore, Mr. Zimmerman's talking points neglected the fact that ABC, not the DEA, is responsible for maintaining an effective program to prevent diversion.

This private face also can be seen in the "comprehensive 2015 revision" referenced in Mr. Collis' Congressional testimony. In 2015, ABC engaged FTI Consulting, Inc.'s Health Solutions Practice ("FTI") to:

> review, map and document current state processes; identify any critical process gaps and areas for improvement; develop recommendations for process improvements and gap remediation; and scope the initial functional requirements for a technology solution(s) or technology enhancements identified as part of the recommendations.[703]

The result was that FTI provided AmerisourceBergen with a list of forty findings, many of which were assigned to David May, an ex-DEA employee and ABC's Vice President of Security and Diversion Control.[704] Mr. May,

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[698] *See* Collis Statement at 3-4.

[699] *See id.* at 7-8.

[700] In October 2018, Mr. Zimmerman was replaced by Kathy Gaddes, who is Executive Vice President and Chief Compliance Officer for ABC. *See* AmericsourceBergen, Kathy H. Gaddes at https://www.amerisourcebergen.com/abcnew/people/kathy-gaddes (last accessed Jan. 22, 2019). Prior to that she was Executive Vice President and Chief Human Resources Officer. Mr. Zimmerman's replacement coincides with ABSG's September 2018 AKS settlement. *See* Discussion *infra*.

[701] *See* Chris Zimmerman Deposition, 139 (Aug. 3. 2018).

[702] *See* Board Talking Points at 2.

[703] *See* FTI Consulting, Inc., Health Solutions Practice, *AmerisourceBergen Corporation CSRA Process Review, Phase 1 Narrative Report*, 3 (Aug. 25, 2015), ABDCMDL00274105 ["FTI Narrative"]

[704] See FTI Consulting, Inc., Health Solutions Practice, CSRA Process Review – Findings Matrix (Aug. 25, 2015), ABDCMDL00250024 ["FTI Findings"]. Although specific findings from the FTI report are discussed throughout this section, in general FTI highlighted issues with ABC's anti-diversion program including a lack of resources, a lack of formal training, excess workloads, and administrative demands, as well as inconsistent policies and communications.

however, did not agree with most of FTI's findings as evidenced by the notations on the findings matrix and his deposition testimony.[705] As Mr. May recounted in his deposition, "in the context of this report provided by an outside consultant that essentially did a snapshot into the work that CSRA was performing -- I was on the ground performing that work every single day [a]nd I don't agree with the characterizations in the report."[706] Not only did Mr. May disagree with the findings, but ABC also did not implement any changes in its policies and procedures as a result of the FTI report.[707]

This private face can also be seen in AmerisourceBergen's Code of Ethics and Business Conduct. The Code contains the normal company admonishments to employees:

- act ethically;
- comply with the law;
- protect the Company's tangible and intangible assets; and
- respect and ensure the safety of all Company employees.[708]

Despite its public acknowledgment by ABC's Chairman, President, and CEO, that distributors have a role in preventing diversion and the company takes this role seriously, AmerisourceBergen's Code does not prioritize its responsibilities regarding controlled substances and only briefly mentions controlled substances in passing noting:

> Furthermore, each operating company may have additional policies and procedures that further clarify your ethical and legal obligations. For instance, associates of some business units of the Company are also required to comply with the Company's Marketing Code of Conduct. Other associates, **including all compliance-critical associates with ongoing authorization to access controlled substances**, and certain key management personnel, are subject to additional compliance training and annual screening.[709]

Instead of focusing on preventing controlled substances diversion, the Code spends proportionately more time on covering social media, company ownership of intellectual property, and compliance approval forms for gifts and donations. The Code also states that associates (employees) can be disciplined for not reporting suspected violations but does not impose an affirmative duty to report violations.[710] Thus, the Code itself illustrates this public/private cultural paradox in which ABC's actions surrounding controlled substances compliance are not aligned with the public perception it tries to maintain.

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[705] *See, e.g.,* FTI Findings at 2 ("No Further Action Required: There is complete visibility in the process, training and rationale [for adjudicating held orders.]); David May Deposition, 142:15-23 (Aug. 4, 2018).

[706] *See id.*

[707] *See* D. May Deposition at 149:2-5 ("And so the answer to your question, did I make changes to policies and procedure as a result of this document is no."); *but cf.* D. May Deposition at 153:1-3 ("All that aside, I conducted my own review and we made changes to the program.").

[708] *See* AmerisourceBergen, *Code of Ethics and Business Conduct*, 3 (Mar. 2017), P-138 ["ABC COE"].

[709] *See* ABC COE at 3 (emphasis added).

[710] *See* ABC COE at 5.

This goes beyond just the Code and permeates other ABC policies as well. For example, ABC states that "each associate has a responsibility by federal administrative law … to report any diversion of any listed chemical or controlled substance from our company **by fellow associates**."[711] However, the Code does not require associates to report diversion or suspected diversion by **customers** as envisioned by the CSA. Therefore, the Code demonstrates that when ABC looks at diversion, it is more concerned with diversion by the company's employees that directly affects ABC's profitability, rather than diversion by its customers once the controlled substances are sold.

Consequently, ABC's company culture and its "private face," have hampered ABC's ability to reflect on the effectiveness of its program objectively. They also have created a contradictory paradigm in which ABC, on the one hand, maintains its program is fully compliant with the DEA's requirements, and yet, on the other hand, the company makes periodic changes to the CSRA organization and the program's core. Consequently, ABC's attempt "to walk in two worlds" simply has hamstrung its ability to develop and implement an effective program to detect and report suspicious orders and to potentially alleviate the diversionary activities undertaken by some of its customers.

11.4.2 AmerisourceBergen has failed to optimize its organizational connections between ABC's controlled substances program and ABC's Corporate Compliance program.

Since its inception in 2001, AmerisourceBergen has had three Chief Compliance Officers. The three are:

- Debbie Schwartz, Associate General Counsel & Chief Compliance Officer (2001 to 2012);[712]
- Christopher Zimmerman, Senior Vice President Corporate Security and Regulatory Affairs & Chief Compliance Officer (2012 to 2018);[713] and
- Kathy Gaddes, Executive Vice President and Chief Compliance Officer (2018 to present). [714]

Of the three, it is Mr. Zimmerman's tenure as Chief Compliance Office beginning in 2012 that has had the greatest detrimental effect on the company's controlled substances and corporate compliance programs. With the expansion of Mr. Zimmerman's role to head up both the controlled substances and corporate compliance programs, AmerisourceBergen had an opportunity to dramatically raise the profile and importance of controlled substances compliance within the organization. Unfortunately, Mr. Zimmerman and ABC squandered that opportunity.

Despite having regular contact with ABC's Board of Director's Audit Committee, Mr. Zimmerman failed to use those interactions to highlight and address controlled substances compliance. As he testified in his deposition,

[711] *See* AmerisourceBergen, *Associate Responsibility to Report Diversion,* S&RC 12.01 (May 13, 2016) (emphasis added) (The policy was first made effective on 10/1/2005), ABDCMDL00156065.

[712] *See* D. Schwartz LinkedIn Profile, https://www.linkedin.com/in/debbieswartz/ (last accessed Jan. 26, 2019).

[713] *See* C. Zimmerman Deposition at 20:18-20; *see also* AmericsourceBergen, Kathy H. Gaddes at https://www.amerisourcebergen.com/abcnew/people/kathy-gaddes (last accessed Jan. 22, 2019).

[714] *See* AmericsourceBergen, Kathy H. Gaddes at https://www.amerisourcebergen.com/abcnew/people/kathy-gaddes (last accessed Jan. 22, 2019).

Mr. Zimmerman did not routinely discuss diversion control.[715] In fact, it appears that Mr. Zimmerman and his team only briefed the Board on controlled substances one time in August 2017. Although the exact reason for this lack of periodic briefings is not clear, Mr. Zimmerman's admission is an indication that he and ABC's Board of Directors either did not appreciate the level of risk posed by ABC's lack of controlled substances compliance both to the public and to the company, or did not view the company's compliance efforts in this area as particularly important.

In addition, despite Mr. Zimmerman also being ABC's Chief Compliance Officer, evidence suggests that CSRA, in general, lacked credibility and authority within the AmerisourceBergen organization. FTI highlighted this in its 2015 CSRA review noting "[t]here is also an impression that the Specialty Group and sister companies **do not recognize CSRA as an authoritative body** and do not have **any meaningful contact or communications** with CSRA."[716]

FTI's report is not the only evidence of the weakness of CSRA. It also can be seen during the development of CSRA talking points for the Regional Vice Presidents outlining ABC's new threshold approach in 2009. The new threshold approach involved factoring both customer size and controlled substances purchasing ratios.

Describing the new approach, Mr. Zimmerman wrote that "**[i]f this [approach] is acceptable**, we will undertake a review of the top 25 purchasers of HY and OX and adjust thresholds accordingly … ."[717] Although the CSRA and Mr. Zimmerman had full responsibility for the controlled substances compliance program, this statement shows that Mr. Zimmerman felt he needed approval to act. This is a sign that either Mr. Zimmerman did not understand his role as Chief Compliance Officer or that he knew CSRA's actual authority was extremely limited.

A good compliance officer normally does not seek approval to act within the department's delegated authority, especially when the action can be easily modified or reversed (e.g., no lasting impact). Therefore, I would have expected a statement that he was implementing the new threshold approach after engaging in appropriate consultation with the business, rather than his statement here.

11.4.3 While the number of personnel assigned to AmerisourceBergen's CSRA function grew over time, the company did not utilize those resources to its best advantage.

From a total paper headcount perspective, AmerisourceBergen has a sizable number of resources in its Corporate Security and Regulatory Affairs ("CSRA") function when compared to its peers (e.g., Cardinal and McKesson). However, the numbers alone do not tell the whole story. First CSRA has more duties than just handling controlled substances compliance and second, CSRA's organizational structure is so convoluted that the division of responsibilities within the CSRA team is unclear. The result is that the organizational structure of CSRA is a net negative that contributes to program inefficiency and inconsistency.

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[715] *See* C. Zimmerman Deposition at 252:4-253:6.

[716] *See* FTI Narrative at 8 (emphasis added).

[717] *See* Memorandum from C. Zimmerman to E. Hazewski, *et al.*, *RVP Talking Points*, 2 (Jan. 19, 2009) (emphasis added), ABDCMDL00000169 ["RVP Talking Pts. 2009"].

Within ABC, the CSRA department has an expansive role that includes diversion control, regulatory compliance and auditing, investigations, complaints, business continuity and physical security.[718] In May 2012 those duties expanded once more when Mr. Zimmerman become ABC's, Chief Compliance Officer.

In the areas of diversion control, the CSRA Diversion Control Group was first established in 2007.[719] From 2008 to 2014, the group was headed up by Edward Hazewski, Director of Diversion Control and Security.[720] Although at the outset the Diversion Control Group reported directly to Mr. Zimmerman as the head of CSRA, its reporting relationship has devolved several times over the years, including reporting for a time to the Drug Distribution Group, thereby reducing its visibility within CSRA. Nor did the changes translate into significant headcount increases. The group always has been small ranging in size from a minimum of 3 in 2009[721] to a maximum of 17 in 2017.[722]

In stark contrast, CSRA's Drug Distribution Group, headed by Stephen Mays, ranged in size from a minimum of ~32 in 2009[723] to a maximum of ~43 in 2017.[724] As recounted by Mr. Mays, from 2007 to 2015, the Drug Distribution Group (currently known as the Pharmaceutical Distribution and Global Sourcing Group) had primary responsibility for the Order Monitor Program or OMP.[725] Therefore, since 2007 the Drug Distribution Group has played a significant role in ABC's controlled substances compliance program.

Even when most of ABC's diversion control efforts were centralized under the auspices of David May, Vice President of Security and Diversion Control starting in 2014 and completed 2015, ABC failed to clarify roles and responsibilities sufficiently. Mr. May, together with his seven direct reports in 2015:

> Directs overall Diversion Control Program for ABC and all subsidiaries. Initiates and manages program initiatives to ensure that the drug company and the other business units that distribute controlled substances and listed chemicals are operating within established law and regulation. Tracks and responds to changes in prescription drug abuse trends and regulatory requirements. Assists legal in preparing and responding to official state and federal requests and subpoenas for information and documentation. Provides information and training to customers relative to diversion control best practices. Evaluates customer due diligence investigations and take appropriate actions to prevent illegal diversion. Develops and manages anti-diversion education and training programs tailored to company business units and functions. Maintains working relationships with drug manufacturers and other industry stakeholders.[726]

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[718] *See* FTI Narrative at 6.

[719] *See* BOD Talking Points at 2.

[720] *See* Edward Hazewski Deposition, 21:4-12 (Oct. 25, 2018).

[721] *See* CSRA Organizational Chart, Policy 1.1 (Oct. 1, 2009), ABDCMDL00364269.

[722] *See* CSRA Organization Chart, ABDCMDL00017114 (Oct. 2017).

[723] *See* CSRA Organizational Chart, Policy 1.1 (Oct. 1, 2009), ABDCMDL00364269.

[724] *See* CSRA Organization Chart, ABDCMDL00017114 (Oct. 2017).

[725] *See* Stephen Mays Deposition, 66:21-67:7 and 200:24-202:23 (Oct. 24, 2018) (Stephen Mays was the top diversion control person in 2007).

[726] *See* CSRA, Diversion Program Assignments, 1 (May 2015), ABDCMDL00247169; *see also* Senior Director, CSRA

Even during the centralization period (2014-2015), when CSRA began outlining the new Diversion Control and Federal Investigations role, it was clear that Pharmaceutical Distribution would continue to play a prominent, if unclear, role in ABC's diversion prevention program.[727] For example, as the responsibility for customer communications illustrates, this responsibility was vested jointly between Diversion Control and Pharmaceutical Distribution, but with no clear delineation of roles and responsibilities.[728] As FTI noted in its report:

> The CSRA resources that we interacted with were very knowledgeable with respect to their subject areas, although at times it was challenging to nail down their specific scope of responsibilities. Because **the roles and responsibilities of CSRA personnel are somewhat ill-defined**, CSRA team members sometimes end up performing activities outside of their purview which **detracts from the utilization of these resources**.[729]

Further complicating matters was the reliance by CSRA on the ABC sales team, which in addition to interacting directly with customers and growing the company's "top line", also was responsible for collecting the Form 590s, a major part of ABC's due diligence efforts[730], as well as reporting "red flags" of diversion back to CSRA, but these "extra duties" were not part of the overall sale representatives' compensation plan.[731] According to Nathan Elkins, like most sales teams, ABC's representative compensation was tied to meeting quotas (e.g., sales targets).[732] However, up until FY 2017, the sales of controlled substances, including opioids, were included in the sales representatives' compensation plan.[733] It was only after 2017 that opioids were "carved out" of the mix.[734] Therefore, before the FY 2017 "carve out," greater opioid sales could lead to greater compensation for ABC sales representatives.

The use of sales targets and quotas by a distributor or pharmaceutical company is not *per se* wrong. However, in the case of ABC, such a heavy reliance on the sales team to meet CSRA's compliance needs without providing a corresponding compliance performance objective disincentivized ABC's sales team from reporting compliance issues. It follows the well-worn corporate maxim that what gets measured and rewarded gets done.

Diversion Control and Federal Investigations, 2014 Performance Work Plan (Apr. 29, 2014), ABDCMDL00158306 and ABDCMDL00158307.

[727] *See, e.g.,* Email from C. Zimmerman to E. Hazewski and S. May., FW: Updated (Feb. 12, 2014) ("we decided … [to] get [in] a room and come to a consensus of who is going to do what."), ABDCMDL00291410; CSRA Task Survey, ABDCMDL00246985; E. Hazewski, *Diversion Control Program Roles* (Feb. 10, 2014), ABDCMDL00291411.

[728] *See* E. Hazewski, *Diversion Control Program Roles* (Feb. 10, 2014), ABDCMDL00291411; FTI Findings at 20.

[729] *See* FTI Narrative at 7-8 (emphasis added).

[730] For a description of and discussion about the CSRA Form 590s *see infra* Section 10.5.4.

[731] *See* Nathan Elkins Deposition, 225-230 (Nov. 14, 2018); *see id.* at 152:6-15.

[732] *See id.* at 135:14 to 136:16. According to his LinkedIn profile, Mr. Elkins, currently an ABC Sales District Director, was a Retail Account Manager from 2005 to 2011. *See* Nathan Elkins LinkedIn Profile, https://www.linkedin.com/in/nathan-elkins-8a1b0718/ (last accessed Mar. 16, 2019).

[733] *See id.* at 142:23-143:7.

[734] *See id.* at 143:1-7 and 144:4-9.

Finally, poor utilization and the lack of clear responsibilities ultimately increased workload and reduced the program's overall effectiveness.

11.5 Program Core – Requirements, Education, Detection & Corrections

11.5.1 Prior to 2007, AmerisourceBergen's two-part controlled substances program was at best rudimentary, and not compliant with DEA regulatory requirements.

Like other distributors, ABC's pre-2007 controlled substances program had an extremely limited focus. The program's primary objective was to notify the DEA about suspicious orders rather than to create a holistic anti-diversion program. According to Mr. Zimmerman, in 1997, Bergen Brunswig, ABC's predecessor, revamped its order monitoring program ("OMP") "to account for the individual pharmacies purchasing levels by volume."[735] Prior to that date, both large and small pharmacies were lumped together into a single peer group.[736]

During that period (1997 to 2007), ABC did not hold or investigate potentially suspicious orders (or as ABC referred to them - orders of interest), as the practice was to ship the orders at night, and then the next day any orders that were identified as suspicious were reported to the DEA.[737] Although the process was a two-step process ("It was an excessive order report that was produced monthly to send to DEA, and then we also had a manual process at the distribution centers where the order fillers would identify suspicious orders and report those.") the clear emphasis was on processing orders as quickly as possible to meet customer demands.[738]

A. Excessive Order Reports

As the primary SOM control pre-2007, excessive order reports were generated when an ABC customer exceeded its threshold or monthly allocation for a controlled substance. According to Stephen Mays, Senior Director, Pharmaceutical Distribution and Global Sourcing, an "excessive order" was "an order that would have exceeded those parameters that were built into the system to produce those reports," while a "suspicious order" was "[a]nything that met those guidelines and the regulation that could be a suspicious order."[739] Therefore, according to Mr. Mays, not every excessive order was a suspicious order.

Underpinning the excessive order reports were product thresholds. According to Mr. Zimmerman, ABC has always employed some form of thresholds.[740] Prior to 1998, ABC simply generated an average volume per

[735] *See* BOD Talking Points at 2.

[736] *See* BOD Talking Points at 2.

[737] *See* Chris Zimmerman Deposition at 110:16-22.

[738] *See* C. Zimmerman Deposition at 108:19-109:4.

[739] *See* Steve Mays Deposition, 131:5-16 (Oct. 24, 2018).

[740] *See* C. Zimmerman Deposition at 111:12-16.

month per drug category and then added the multiplier of three.[741] Orders above that level would be on the excessive order report.[742]

Beginning in 1998 through 2007, ABC refined its threshold calculations even further, but still retained the multiplier of three. According to Mr. Zimmerman, ABC examined a pharmacy's purchasing history and calculated a rolling four-month average that was then tripled to create the suspicious order threshold.[743]

While this new calculation improved upon the earlier version by reducing the base threshold for smaller pharmacies, the arbitrary tripling of the base threshold for all pharmacies could still allow pharmacies to order excessively large quantities of opioids and other controlled substances without being flagged. Having a more refined "buffer" built into the threshold would have reduced that risk. Given the fact that ABC was not holding, but merely reporting, any excessive orders, having a more refined threshold likely would have achieved nothing during the time period before 2007. However, the lack of a refined threshold together with ABC's failure to hold and investigate excessive orders resulted in a deficient SOM and diversion prevention program during this period.

B. Manual Distribution Center Process

The manual distribution center process (the second step) cannot remedy the deficiencies in ABC's pre-2007 program. Like Cardinal Health, ABC relied on "pickers" to identify potentially suspicious orders. ABC asked its "distribution center employees that work in the cages and vaults if they see an unusually large order or frequency or pattern that they feel could be potentially suspicious, then they are to report that."[744]

However, ABC's policy outlining an associate's responsibility for diversion further undermines reliance on the cage and vault employees as an effective control. According to Policy S&RC 12.01 which initially became effective in October 2005, "each associate has a responsibility by federal administrative law … to report any diversion of any listed chemical or controlled substance from our company **by fellow associates**."[745] This policy does not require associates to report <u>customer orders</u> of unusual size, frequency or pattern. Therefore, at the bare minimum, this policy incompletely covers an employee's affirmative duties pertaining to controlled substances compliance.

11.5.2 AmerisourceBergen's Order Monitoring Program ("OMP") between 2007 and 2016 was rendered ineffective by a combination of poor design and inconsistent application.

In 2007, AmerisourceBergen proceeded to modify its controlled substances compliance program. Mr. Zimmerman described the changes as:

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[741] *Id.* at 121:12-20.

[742] *Id.* at 121:18-20.

[743] *Id.* at 122:13-23.

[744] *Id.* at 114:22-115:6.

[745] *See Associate Responsibility to Report Diversion,* S&RC 12.01 (emphasis added).

> DEA wanted us to include a more in-depth due diligence process in addition to ensuring that we only distribute products to licensed individuals. And they also wanted us to modify our suspicious order monitoring program to stop orders that we believed -- stop orders that could possibly be suspicious and then to any suspicious -- any order we deem suspicious should not be shipped.[746]

Although AmerisourceBergen began implementing these changes in 2007, the DEA, in fact, had given ABC notice two years earlier that its program was deficient, and these items needed improvement.

AmerisourceBergen met with the DEA in Washington, D.C. in August 2005. During that meeting, the DEA reminded AmerisourceBergen of several key compliance points including:

- Simply reporting suspicious orders does not relieve a distributor of the need to maintain effective controls against diversion;[747]
- The DEA cannot tell a distributor if an order is suspicious and so distributors must determine which orders are suspicious and make sales decisions;[748]
- Invalid prescriptions are not for legitimate medicals needs and thus are diverted, regardless of where filled;[749] and
- Any distributor "who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately."[750]

Thus, as of 2005, the DEA placed ABC on notice that its current program was inadequate. However, like both McKesson and Cardinal Health, AmerisourceBergen simply did not implement the necessary changes. It was not until <u>two years later</u> when the settlement compelled them to do so that ABC began making substantive improvements in its anti-diversion program.

ABC's controlled substances compliance program was outlined by several policy and procedure documents, which are listed at Appendix E, Figure 2.[751] According to FTI, "[f]or the most part, CSRA has good processes in place but struggles with documenting and providing visibility to those efforts [and the] organization suffers from decentralized and segmented tracking and documentation of information and activities, which results in

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[746] *See* C. Zimmerman Deposition at 139:20-140:8.

[747] *See* Meeting with AmerisourceBergen DEA Headquarters, *Internet Pharmacy Data*, 7 (Aug. 10, 2005), ABDCMDL00315887 ["DEA HQ Mtg."].

[748] *See* DEA HQ Mtg. at 8.

[749] *See* DEA HQ Mtg. at 12.

[750] *See* DEA HQ Mtg. at 13.

[751] *See also* AmerisourceBergen Diversion Control Program Policies & Procedures, ABDCMDL00003367 to ABDCMDL00003429; Email from D. May to C. Conneely, *et al.*, *Diversion Control Policies* (Jan. 15, 2015) (Caroline Conneely was with FTI), ABDCMDL00251385 to ABDCMDL00251406.

limited reporting and tracking of workload, as well as a lack of access to timely and comprehensive information across CSRA."[752]

A simple review of the list in Appendix E, Figure 2 supports that finding. ABC's diversion control policies and procedures are contained within two different and separate series. One series starts with the prefix "DCP" and the other "CRSA." However, the documents are not formatted consistently across the series. For example, the CSRA series lists authors while the DCP series does not. Also, the DCP series consistently notes revision history while the CSRA series does so on an inconsistent basis. Finally, both series do not contain any linkage to a document's approval either by listing the names of the approvers or referencing a Document Change Notice ("DCN").

When taken together, both series contain documents covering the same topics, but containing different provisions, and there is no clear indication of how they link together. For example, there are two policies for the Order Monitoring Program (DCP-12.2.0 and CSRA 2.12). The purpose of DCP-12.2.0 states it is:

> to establish the AmerisourceBergen Drug Corporation ("ABDC") Order Monitoring Program ("OMP") as a component of the broader Diversion Control Program, which is designed to prevent, detect and investigate the potential diversion of controlled substances and listed chemicals (hereafter referred to collectively as Controlled Substances) into other than legitimate medical, scientific and industrial channels. This policy establishes the requirement for ABDC's reviewing orders of Controlled Substances placed by ABDC customers in order to identify and investigate potentially suspicious orders and for reporting suspicious orders to the Drug Enforcement Administration ("DEA") and state authorities, as appropriate.[753]

The CSRA OMP policy's purpose states:

> To ensure compliance with applicable state and federal regulations, AmerisourceBergen Corporation (ABC) has designed this program to review the ordering activity of its customers to identify possible excessive or suspicious orders of controlled substances and listed chemicals.[754]

Although the CSRA policy pre-dates the DCP policy (2005 versus 2007), the list of policy and procedure references in the DCP policy fail to list the CSRA policy even though the DCP policy seems to establish the mandate for the OMP.[755] Overall, ABC has created unnecessary complexity through confusing sets of program documentation, which makes it hard to decipher exactly how ABC's program operated and for ABC to establish that their program indeed was effective.

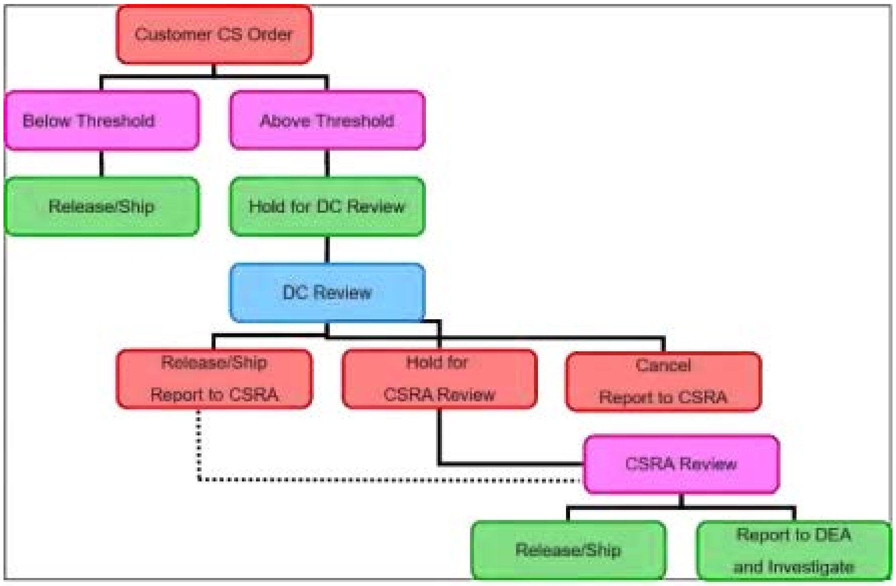
[752] *See* FTI Narrative at 9; *see also* Email from Steve Mays to D. May and C. Zimmerman, *FW: DEA Audit Tracking* (May 16, 2017), ABDCMDL00253868 (Post FY 2007, the DEA audit history spreadsheet records six DEA distribution center audits noting poor recordkeeping violations).

[753] DCP-12.2.0 at § 1.1, ABDCMDL00003367 at ABDCMDL00003380.

[754] *See* CSRA 2.12 at "Purpose."

[755] DCP-12.2.0 at § 3, ABDCMDL00003367 at ABDCMDL00003380.

Figure 4 AmerisourceBergen OMP



The diagram above outlines how AmerisourceBergen's order monitoring program ("OMP") operated beginning in 2007, showing the division of responsibilities between the Distribution Centers and CSRA.[756]

Beginning in 2007, ABC's OMP was based on the following parameters:

[redacted][757]

Despite AmerisourceBergen's efforts, including its perception that the DEA somehow endorsed it, the OMP had multiple inconsistencies and weaknesses.

A. Customer Size & Controlled Substances Ratio

The heart of ABC's thresholds from 2007 to 2016 was predicated on the dual concepts of customer size and the ratio of controlled substances purchases to all pharmaceutical purchases. It is the interplay between these concepts and how CSRA applied them that ultimately resulted in the lack of a consistent, and hence effective, SOM and controlled substances program.

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[756] *See* Stephen Mays, *ABC Diversion Control Program effective June 25, 2007,* 18 (Jun. 25, 2007), ABDCMDL00000101.

[757] *See* AmerisourceBergen, *Diversion Control Enhancements – Internal Update*, 6-7 (May 6, 2016), ABDCMDL00276831 ["DC Enhancements 2016"].

While customer size was supposedly based on dollar volume, the contemporary CSRA guideline for threshold review noted that the size determination is "based upon sales volume and controlled substances (CS) ratio, CSRA has been able to place all retail pharmacy accounts into one of four categories."[758] When asked about this statement, Mr. Zimmerman failed to provide a clear answer as to what ABC meant.[759]

Without a credible contrary explanation, it appears that CSRA was making size determinations based upon both dollar volume and product mix in such a manner as to set thresholds sufficiently high enough to avoid the need to report orders as suspicious. Given the fact that that the basis of ABC's thresholds was volume and product mix with no other potential circumstances indicative of diversion as outlined by the DEA in 2006 [760] together with the buffer of three times the average volume, ABC effectively ensured that the thresholds rarely would be hit, thus avoiding the need to hold orders.

Mr. Zimmerman's 2009 RVP Talking Points further support this contention. The RVP Talking Points detail the interplay between customer size and controlled substances ratio.[761] There were four different permutations: high volume/low controlled substances ratio, high volume/high controlled substances ratio, low volume/high ratio and finally low volume/low ratio. [762]

Regardless of which permutation a retail customer fell under, CSRA had the ability to raise customer thresholds. For customers with a low ratio of controlled substances (presumably less than [redacted] customer average), CSRA apparently considered raising thresholds to be normal.[763] For example, in the case of small retail customers (less than $100K total monthly volume) with a low ratio of controlled substances, ABC could raise their thresholds simply based on "the assumption that their total monthly dollar volume rises along with their volume."[764] This assumption presumes that just because overall sales rise, controlled substances sales will rise too. That connection does not appear to be supported by any evidence, and in fact, it is possible to conceive of reasons why a pharmacy's total monthly dollar volume might rise, but controlled substances sales do not.

In addition, it is important to note that CSRA's default thresholds were high at the outset. For example, for a small retail customer doing less than $100,000 per month, their unadjusted monthly oxycodone threshold was set at [redacted] dosage units and their hydrocodone at [redacted] dosage units. As discussed previously in this report, the DEA beginning in 2006 believed that the threshold level triggering further investigation was 5,000 dosage

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[758] *See* Guidelines for Threshold Reviews, 1 (Jun. 30, 2007) (The date was established in C. Zimmerman's Deposition at 284:10-12), ABDCMDL00000099.

[759] *See* C. Zimmerman Deposition at 286:23-288:6.

[760] *See* Letter from J. Rannazzisi to All Registrants, 3 (Sep. 27, 2006).

[761] *See* Memorandum from C. Zimmerman to E. Hazewski, *et al.*, *RVP Talking Points*, 1 (Jan. 19, 2009), ABDCMDL00000169 ["RVP Talking Pts. 2009"]. The "ratio" is the same thing as "product mix." In other words, what percentage of the pharmacy's total prescription volume are made up by controlled substances.

[762] *See* RVP Talking Pts. 2009 at 1-2.

[763] *See* RVP Talking Pts. 2009 at 1-2.

[764] *See* RVP Talking Pts. 2009 at 1.

units on average.[765] Thus, [redacted] Therefore, in the eyes of the DEA's limits, ABC's basic unadjusted thresholds started out at suspicious order levels.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]. In short, Mr. Zimmerman's proposal voided an established SOM control and abrogated CSRA's order monitoring oversight responsibilities.

C. OMP – Setting the Record Straight

In January 2012, ABC distributed an internal document entitled "Order Monitoring Program (OMP) Setting the Record Straight" which combined a high-level overview, frequently asked questions and talking points surrounding changes to OMP and deployment of SAP to manage ABC customer accounts.[771] The document, which was updated once more in October 2012, did anything but set the record straight.[772] Overall the October revisions simply "watered down" the controls around suspicious order monitoring program.

Both the January and October versions reference the fact that thresholds were now being applied by DEA registration number and not account number.[773] Prior to the 2012 SAP upgrade, multiple ABC accounts could have the same DEA registration number.[774] Under the new system, ABC would apply the largest account threshold to all accounts using the same DEA registration number.[775] Therefore, the multiple accounts received a generic (and highest) threshold rather than thresholds tailored to each customer. As Ed Hazewski testified, he, and thus ABC, did not see any problem with this even though ABC could artificially inflate thresholds for some customers.[776]

The October version also removed the following language:

> Thresholds are set for each drug family: Amphetamines, morphines, codeines, etc. This means that an account can reach their threshold several times a month depending on the family drug that exceeds the threshold. When a **THRESHOLD REVIEW** form is submitted, it covers one drug

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[770] *Id.* (emphasis added).

[771] *See* Memorandum Order Monitoring Program (OMP) Setting the Record Straight, 1 (Jan. 30, 2012), ABDCMDL00002405. The document was sent under the auspices of Edward Hazewski. *See* Email from E. Hazewski to T. Cooper, Document (Jan. 16, 2010), ABDCMDL00280993 ["Setting the Record Straight Jan."].

[772] *See* Memorandum Order Monitoring Program (OMP) Setting the Record Straight (Oct. 3, 2012), ABDCMDL00280994 ["Setting the Record Straight Oct."].

[773] *See* Setting the Record Straight Oct. at 5.

[774] *See* Setting the Record Straight Jan. and Oct. at 5, FAQ #2.

[775] *See* Setting the Record Straight Jan. and Oct. at 5, FAQ #2.

[776] *See* E. Hazewski Deposition at 268:5-12.

> family **unless** more than one family is indicated on the form. **Requests for blanket threshold increases across all drug families are not permitted**.[777]

The new version eliminated the use threshold review forms and the documented rationale for why the increase was needed.[778] It also appears that blanket threshold increases across all drug families were now permitted.

The October version also eliminated FAQ #5 in the January version which stated:

> OMP is based on order quantity, and it is meant to identify suspicious ordering patterns. The **DEA does not focus on what we ship to our customers**; they require us to evaluate what was ordered because the attempt to place an order is what can identify suspicious orders.[779]

Beyond being a simple misstatement of the law and regulations, the answer implies that if the order is not flagged as suspicious, ABC could adjust the shipment after the order cleared to accommodate customers. What is even more troubling is that this advice is being provided by the individual (Edward Hazewski) who headed up the Diversion Control team from 2008 to 2014.[780]

The October version of the communication professed that with the implementation of SAP, Distribution Center ("DC") discretion to release orders held due to OMP was being curtailed so that only "under limited circumstances" could the DC release held orders.[781] In reality, the October amendments allowed the DC to carry on releasing orders above the threshold.

According to the January version, the DC could release orders exceeding the thresholds by 10% for the first order, by 25% on the second order provided the Account Manager submitted a Threshold Request form to CSRA, and by 75% for the third order.[782] After SAP, all DC discretion to release orders above the threshold was revoked.[783] According to the January version, this was because:

> [h]istorically, each DC had the ability to review held orders and apply their best judgment in releasing individual orders. Most sales associates have had accounts exceed their thresholds at some point in time; however, the DC had the ability to "make the call" after conducting their review which led to customers receiving their orders. As we deploy SAP to our DCs, the OMP management process becomes more systemic and less arbitrary. This is by design.[784]

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[777] *See* Setting the Record Straight Oct. at 5, FAQ #2 (emphasis in the original).

[778] *See* Setting the Record Straight Oct. at 5, FAQ #3 (The October version eliminated the following sentence, "[t]he Account Manager can complete and submit a Threshold Review Form to ensure that this information [explaining the situation] is provided to Corporate Security and Regulatory Affairs.").

[779] *See* Setting the Record Straight Jan. at 5, FAQ #5.

[780] *See* E. Hazewski Deposition at 21:5-12.

[781] *See* Setting the Record Straight Oct. at 7, FAQ #10.

[782] *See* Setting the Record Straight Jan. at 6-7, FAQ #10.

[783] *See* Setting the Record Straight Jan. at 7, FAQ #10.

[784] *See* Setting the Record Straight Jan. at 7, FAQ #10.

The October version removed the historical language above, as well as the requirement for a Threshold Review form to be filed with CSRA and allowed DC's to continue filling orders under the unspecific "limited circumstances" criterion.[785] The net result of the October change was to dial back CSRA's visibility of the DC's threshold overrides and provided the DC's ability to approve overrides with less accountability. Therefore, while this change was good for sales, it negatively impacted the SOM program.

The October version also removed any language prohibiting disclosure to accounts that ABC was reporting rejected orders to the DEA as suspicious. In particular, the October version deleted the following sentence: "Notifying a customer that they have been reported to the DEA or State would defeat the purpose of the monitoring program."[786] I can only conclude that ABC made the change to allow its sales force to provide customers with valuable coaching on how to avoid their orders being labeled as "suspicious," thereby undermining the SOM program even further. This is one of clearest instances that ABC cared more about preserving the customer relationship than exercising its statutory and regulatory obligations.

D. Low-Volume Accounts

In approximately July 2013, ABC began to work on a campaign to target its low-volume accounts. These were accounts with a low dollar volume (e.g., <$100K total monthly volume), in other words, small retail pharmacies, but with a high [redacted] ratio of controlled substances.[787] Internal sales talking points were developed using the threat that "your percentage of C2 orders is high and may be deemed suspicious by either our OMP system or regulatory authorities. This puts your account with ABDC at significant risk of closure or exposure to regulatory and enforcement agencies actions."[788]

The goal was not to lower the ratio of controlled substances purchases, but rather to have the pharmacy "make ABDC your primary wholesaler and shift all purchases to us [ABDC]" because "[i]ndependent pharmacies come to AmerisourceBergen because they know that by taking full advantage of our product offerings, resources, and expertise, they will be able to attract more patients, retain existing patients and improve their operating efficiencies."[789] In other words, AmerisourceBergen would continue supplying these pharmacies with controlled substances at their usual levels provided they could get the controlled substances ratio down by purchasing a more non-controlled product from ABC. Neither Messrs. Zimmerman nor Mays in their depositions could provide an alternative rationale for the document.

Setting aside the clearly unethical stance of using potential compliance violations to intimidate customers, AmerisourceBergen was not engaging in this program because it was concerned about the diversion of controlled substances, as it publicly professed, but rather ABC was engaging in a good, old fashioned switch program using a negative incentive in place of the more commonly used positive ones. ABC was attempting to increase its market share among the small retail pharmacies while maintaining and increasing its profits.

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[785] *See* Setting the Record Straight Oct. at 7, FAQ #10.

[786] *See* Setting the Record Straight Oct. at 7, FAQ #11.

[787] *See* C. Zimmerman memorandum to E. Hazewski, *et al.*, *RVP Talking Points*, 1 (Jan. 19, 2009), ABDCMDL00000169.

[788] *See* Sales Talking Points, Low-Volume Accounts (Jul. 2013), ABDCMDL00278212.

[789] *See* Sales Talking Points, Low-Volume Accounts (Jul. 2013), ABDCMDL00278212.

Once more, in August 2017, ABC re-visited the problem with customers utilizing AmerisourceBergen as a secondary distributor for purchasing controlled substances. ABC looked at preventing customers from purchasing four high-risk drug families (including hydrocodone solid, hydromorphone solid, oxycodone 30 mg solid and oxycodone solid) from ABC as a secondary distributor.[790] ABC analyzed the impact of this potential alteration to its program from the perspective of dosage units and dollar volume. The change in its business would have resulted in a decrease of 76,393,904 dosage units of just the four drug families considered – roughly 35.7% of the company's business in those four drug families.[791] The financial impact to ABC's total controlled substance sales by removing four drug families included a loss of almost $71 million or roughly 21.9% of ABC's total controlled substance sales.[792] Predictably, ABC chose not limit the ability for its customers to purchase these four drug families from ABC as a secondary supplier.[793]

However, ABC, with the help of its own compliance staff, undermined its own SOM program by providing a "work around" to the product mix control. For example, a top purchaser review of BSD Inc. Save Discount Drugs was conducted in January 2010, three years after BSD's threshold for benzodiazepine anxiety solids was set at 75,000 dosage units based on a threshold override in 2007.[794] While the review noted that BSD was a medium volume, high controlled substance ratio account ($170,254 average monthly dollar volume and a [redacted] controlled substances ratio), the review simply noted that the BSD's purchases had not reached the threshold in the past two years after having been raised and simply requested that the CSRA 590 be completed.[795]

11.5.3 AmerisourceBergen's post-settlement customer due diligence program was ineffective as a result of poor design and inconsistent application.

Enhanced customer due diligence was one of the major improvements that the 2007 DEA-ABC settlement was intended to achieve.[796] Yet, in reality, while ABC did establish a "policy" or "process" governing customer account due diligence in May 2007,[797] CSRA did not require centralized customer files until <u>six years later</u> in 2013[798] and did not create implementing procedures until <u>a full ten years later</u> in 2017.[799]

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[790] *See* Email from M. Guerreiro to D. May RE: Secondary Account Review, (Aug. 18, 2017), ABDCMDL00354768; Presentation by ABC, Controlled Substances Limitation Analysis, 2 (undated), ABDCMDL00354771); ABC Chart, OMP of Interest, ABDCMDL00354777.

[791] *See id.* at 3; *see also* Marcellino Guerreiro Deposition, 278:10-284:8 (April 3, 2019).

[792] *Id*.

[793] *Id.*; *see also* M Guerreiro Deposition at 284:22.

[794] *See* Memorandum from K. Kreutzer, *Top Purchaser Review – BSD Inc.* (Jan. 11, 2010), ABDCMDL00158760 ["BSD Top Purchaser Review"].

[795] *See* BSD Top Purchaser Review.

[796] *See* C. Zimmerman Deposition at 139:20-140:8.

[797] *See* Amerisource Bergen, Policy CSRA 3.4 Customer Account Due Diligence, (Feb. 13, 2013) (The original effective date was May 8, 2007), ABDCMDL00251385 at ABDCMDL00251400.

[798] *See* AmerisourceBergen, Policy CSRA 3.5 Customer Due Diligence Documentation (May 10, 2013) ("This is a new policy."), ABDCMDL00251385 at ABDCMDL00251402.

[799] *See* AmerisourceBergen, Procedure DCP SOP-12.1.10 (Jan. 1. 2017).

A. The CSRA Form 590

The 2007 Account Due Diligence Policy was intended "[t]o establish a process of due diligence and on-going screening of New Customer Accounts to ensure AmerisourceBergen (ABC) only services Customer Accounts that comply with Federal and State Regulations as well as ABC Policy."[800] The same document, however, states "that the following policy applies …" and that by not distinguishing between a policy and an SOP, authors Messrs. Mays and Hazewski merely confused the situation.[801]

The "process" was to complete the CSRA Form 590 (the retail pharmacy questionnaire), next to have an ABC Business Development Manager ("BDM") conduct a site visit, and then have CSRA "verify" the information and either approve or deny the request.[802] The Account Due Diligence policy mandated that the CSRA 590 was to be completed by the BDM during the site visit.[803] Although originally established for new customers, sometime after 2007, ABC began using the CSRA 590 with existing customers, especially those with expanding or changing business models.[804] However, retail chain pharmacies, defined as pharmacies having more than ten stores, were exempt from having a Form 590 on file.[805]

The importance that ABC placed on the CSRA Form 590 as a critical anti-diversion control was substantial. For example, the CSRA Form 590 itself stressed that the "questionnaire is an official business record subject to review by State and Federal regulatory agencies and stipulated that "[f]orms that are not **complete**, illegible, or not signed will be returned."[806]

As ABC told the House Energy and Commerce Committee:

> The information contained on the questionnaire is the basis for ABDC's due diligence investigation and provides a baseline to measure the pharmacy's ordering habits and to determine any deviation from expected purchasing practices. The questionnaire provides information to ABDC regarding anticipated ordering practices, including, among other things, the amount of controlled substances ordered, the anticipated ratio of controlled vs. non-controlled substances purchased, key prescribing doctors in the area utilizing the pharmacy, the purchasing practices of the pharmacy's customers (i.e. cash, credit, insurance, etc.), and whether another supplier is known to have suspended or ceased controlled substance sales to the customer. The questionnaire also includes inquiries on topics such as high-risk drugs and high-prescribing physicians."[807]

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[800] *See* Account Due Diligence, Policy CSRA 3.4 at "Purpose".

[801] *See* Account Due Diligence, Policy CSRA 3.4 at "Purpose".

[802] *See generally* Account Due Diligence, Policy CSRA 3.4.

[803] *See* Account Due Diligence, Policy CSRA 3.4 at "A. Retail Pharmacy Questionnaire".

[804] *See* C. Zimmerman Deposition at 325:2-12.

[805] *See* C. Zimmerman Deposition at 213:16-214:22.

[806] *See* ABC Form CSRA-590, Information (Apr. 2015) (emphasis added), ABDCMDL00355073; *see also* N. Elkins Deposition at 228:6-10 (confirming the CSRA Form 590 information was "vital").

[807] *See* W.Va. Red Flags Report at 113-114.

B. "Verifying" CSRA 590 Data

Once the site visit was completed and the CSRA 590 filled out, it became CSRA's task to verify the information provided.[808] CSRA verification was limited to reviewing the questionnaire responses, performing internet searches on the information provided, and verifying the customer was not listed on ABC's Do Not Ship List.[809] CSRA verification was limited to using a checklist with a series of "YES/NO" responses with extremely limited space to add pertinent details, and which did not instruct the completer that additional information could be appended.[810] Consequently, the verification performed by CSRA was of little or no utility in determining whether to approve the customer. [811]

Furthermore, while ABC's description of the CSRA Form 590 to the House Energy and Commerce Committee technically was accurate, it neglected to mention that neither the Account Due Diligence Policy or the Form 590 required supporting source documentation be provided concerning pharmacy ordering and dispensing practices, as well as key prescriber habits Therefore, CSRA could not independently verify these critical indicators of potential diversionary customer behavior rendering the CSRA verification step simply a "pro forma" exercise.

As ABC told the House Energy & Commerce Committee, "'ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers.'"[812] ABC further elaborated that it "'collects patient de-identified dispensing reports on an as-needed basis to allow it to investigate and mitigate concerns about possible suspicious behavior by its customers[,]' and that '[c]ustomers may also be asked to provide full dispensing reports as part of new customer due diligence, again to mitigate red flags discovered during onboarding or to properly size the pharmacy as part of the company's Ordering Monitoring Program.'"[813] When pressed further about why it did not routinely request this data, ABC told the Committee "[c]ollecting dispensing data on a routine basis from all pharmacies is not a requirement that is imposed upon the distributor by the governing federal laws and implementing regulations."[814]

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[808] *See* Account Due Diligence, Policy CSRA 3.4 at "D. Account Verification Checklist".

[809] *See* Account Due Diligence, Policy CSRA 3.4 at "D. Account Verification Checklist". CSRA used the CSRA Form 590c to perform the verification. *See* Retail Pharmacy Questionnaire (undated), ABDCMDL00301401; *see also* Customer Verification Checklist (Feb. 9, 2010), ABDCMDL00288989; *see also* Email from E. Cherveny to E. Coldren, *et al.*, FYI: OY Block – Pharmlink, Inc. (10056420/BP6335156), (Sep. 22, 2016), ABDCMDL00246107-109; Email from E. Coldren to M. Guerrairo, FW: DNS List, (Feb. 21, 2018), ABDCMDL00300163-166. Recent examples of ABC's failure to enforce the "Do Not Ship" List.

[810] *See* Retail Pharmacy Questionnaire (undated), ABDCMDL00301401; *see also* Customer Verification Checklist (Feb. 9, 2010), ABDCMDL00288989.

[811] *See* Email from D. May to S. Hartman, *et al.*, RE: Mingo Pharmacy, (Oct. 11, 2017), ABDCMDL00142299. ABC failed to recognize that a customer gave incorrect information on its 590 form until ABC was notified by DEA during an investigation of the customer. However, even then ABC did not terminate the customer.

[812] *See* W.Va. Red Flags Report at 114 (citing *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (2018), Responses to Questions for the Record submitted by Steven H. Collis, CEO, President and Chairman of the Board, AmerisourceBergen Corp.).

[813] *See* W.Va. Red Flags Report at 114.

[814] *See* W.Va. Red Flags Report at 114.

Although ABC's counsel is correct that neither the CSA nor its implementing regulations explicitly require ABC to collect this data, ABC's failure to do so effectively undermined the entire due diligence process rendering it moot. Without independent dispensing reports, CSRA was limited to "verifying that [listed] physicians are in good standing to prescribe."[815] Even that control could be circumvented easily by providing CSRA with a list of physicians in good standing, regardless of whether they were the pharmacy's top prescribers of controlled substances.

However, the flawed process design did not end there. The Account Due Diligence Policy also did not clearly define verification roles and responsibilities within CSRA, nor did it specify the criteria for determining whether to accept or reject an account.

C. CSRA 590 Validation Project

In 2016, the Diversion Control Team began a review project of the CSRA 590s in 2016. The purpose of this project was "to validate that all current ABDC customers authorized to purchase controlled substances have the required due diligence documentation in the file."[816] In its first phase, the "project was to conduct a full review of every ABDC customer authorized to purchase controlled substances and identify any with deficiencies."[817] By August 2016, Phase 1 was complete with the result that "a substantial number of customers have been identified who will be required to have their 590 documentation updated."[818] The CSRA Validation Project spreadsheet listed <u>3,285 customers</u> as having no CSRA Form 590 on file.[819]

D. Process Not Followed

The CSRA Form 590 Due Diligence program is another example of the differing public face and private face of ABC's compliance efforts. Publicly, AmerisourceBergen touted the Form 590s as its improved due diligence effort. Yet, privately, ABC was missing a vast number of customer 590 forms.

This was further compounded by the fact that ABC simply did not follow its declared due diligence process. The CSRA 590 Validation Project shows that ABC was not following the due diligence process established in 2007 in response to its settlement with the DEA. With 3,285 customers having no CSRA 590, ABC clearly did not have adequate controls in place to ensure that the CSRA 590s were complete before approving a new account or as a reference on existing customers. Nor were ABC's controls adequate for the CSRA 590 to be used as a reliable source of information when pharmacy circumstances changed.

ABC also lacked an adequate corrective action process to remedy the large shortfall, as demonstrated by the fact that almost <u>12 months</u> after identifying the "sheer volume" of customers with incomplete or missing CSRA 590s,[820] ABC had managed to bring about 10% of the over 3,200 deficient customers into compliance.[821]

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[815] *See* C. Zimmerman Deposition at 343:3-6.

[816] *See* Email from E. Cherveny to S. Hendrickson, *et al.*, CSRA Validation Project (Aug. 5, 2016), ABDCMDL00159415.

[817] *Id.*

[818] *Id.*

[819] *See* CSRA Form 590 Validation Project Spreadsheet (Jul. 28, 2016), ABDCMDL00159417.

[820] *See* Email from E. Cherveny to S. Hendrickson, *et al.*, CSRA Validation Project (Aug. 5, 2016), ABDCMDL00159415.

Therefore, the compliance efforts that ABC espoused publicly as important were not made a priority within the company.

11.5.4 Like its order monitoring and customer due diligence processes, ABC's investigations process suffered from poor design and lack of consistency rendering it ineffective.

Although the due diligence and investigations process was rolled out in June 2007,[822] it was more than a year later in October 2008, that CSRA implemented a policy governing targeted site visits (i.e., investigations).[823] CSRA created the policy to address "specific concerns found during the course of data review or information received from outside sources."[824] According to the Targeted Visits policy, "CSRA will identify customer locations to be visited based on factors, including but not limited to; Diversion Control Program data analysis; information from ABC personnel, regulatory agencies, or any other sources; and/or at the request of [the] ABC General Counsel."[825] However, it was not routine practice to perform targeted visits on existing customers.[826]

Like other CSRA policies, the Targeted Visits policy failed to outline, except in the most general terms, the factors CSRA used to trigger an onsite visit. Some of the unwritten specific criteria that could trigger a targeted visit involved "the activity of the customer, whether they wanted changes, whether they were, you know, being changed in the program, whether they were increasing sales or changing areas of service."[827]

According to the Targeted Visits policy, the Director or Program Manager of the Diversion control program would "select the CSRA Representative or contractor to conduct the visit based on availability and their proximity to the location in question."[828] In addition to the dedicated investigators and the members of the Diversion Control Team, CSRA also pulled in Distribution Center compliance staff to support investigations.[829] The Director or Program Manager, however, was not required to assure the CSRA Representative or contractor was qualified.

Targeted visits typically were announced visits of limited duration. Although, the policy states that "[s]urveillance visits with no contact of pharmacy personnel may be conducted un-announced," the clear

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[821] *See* Email from D. May to J. Sharkey, *et al.*, FW: CSRA 590 Validation Project (Jul. 7, 2017) ("Unfortunately, as of the date of this writing, we have only received about 10% of the required customer due diligence documents."), ABDCMDL00159415.

[822] *See* C. Zimmerman Deposition at 211:9-12.

[823] *See* Amerisource Bergen, Policy CSRA 2.25 Retail Pharmacy Targeted Visits, (Jun. 17, 2013) (The original policy became effective on Oct. 1, 2008), ABDCMDL00251385 at ABDCMDL00251392.

[824] *See* Targeted Visits, Policy CSRA 2.25 at "Purpose".

[825] *See* Targeted Visits, Policy CSRA 2.25 at "Policy".

[826] *See* C. Zimmerman Deposition at 318:1-4 and 321:4-322:5.

[827] *See* C. Zimmerman Deposition at 209:17-22.

[828] *See* Targeted Visits, Policy CSRA 2.25 at "Overview of Procedure".

[829] *See* C. Zimmerman Deposition at 449:17-451:8.

expectation was that targeted visits required scheduling.[830] Therefore, the typical visit required CSRA to contact the Account Manager to coordinate the visit.[831] The Account Manager then contacted "the owner/pharmacist in charge (PIC), inform him/her of the visit, and ensure that the owner/PIC or their designee will be present on the arranged date in order to give their **undivided attention to the CSRA representative for a minimum of one hour**."[832] The implication was that any fieldwork at the site would be completed in an hour.

Although the policy mandated that the investigator must prepare a summary report "to include all observations or concerns noted during the visit as well as recommendations provided to the DC for correction of deficiencies" and "follow a memo format" there is little evidence to indicating that this was routinely done.[833] For example, in October 2013, Natasha Polster, Director of Pharmaceutical Integrity for Walgreens, met with Joe Tomkiewicz in ABC's Diversion Control Team to go over the entire order monitoring process.[834] In her email report to Rex Swords, Walgreen's Divisional Vice President, Pharmacy Services, Ms. Polster noted [redacted]

CSRA investigations, like the verifications of Form 590, were at best cursory. For example, the House Energy and Commerce Committee noted that in December 2015 ABC failed to investigate Westside Pharmacy before reinstating the pharmacy as a customer.[837] According to the Committee, Westside told ABC that its ability to purchase controlled substances had been either terminated or restricted by a distributor in the past, and the CSRA 590 was provided to ABC on the same day it was terminated by Miami-Luken in response to a DEA Show Cause Order.[838] Furthermore, two of the top five listed prescribers of hydrocodone and oxycodone were the subject of public enforcement actions or had a DEA license that could not be verified.[839] ABC's response was that "'[n]ews searches for prescribing physicians are not a standard part of ABC's new customer review.'"[840]

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[830] *See* Targeted Visits, Policy CSRA 2.25 at "1-Notifications".

[831] *See id.* at "1-Notifications".

[832] *See* Targeted Visits, Policy CSRA 2.25 at "2 Pre-Visit Preparation" (emphasis added).

[833] *See* Targeted Visits, Policy CSRA 2.25 at "6-Reports".

[834] *See* Email from T. Polster to R. Swords, ABC Visit (Oct. 31, 2013), WAGMDL00237263.

[835] *See id.*

[836] *See id.*

[837] *See* W. Va. Red Flags Report at 163.

[838] *Id.*

[839] *See id.* at 163-166.

[840] *Id.* at 166.

11.5.5 Although ABC made additional program modification in 2016, CSRA retained the ability to negate the new controls by simply issuing threshold adjustments.

The basic 2007 program remained largely unchanged until 2016, at which point, ABC made a number of changes.[841] These changes mirrored the findings in FTI's report which showed ABC's program had poor documentation and inconsistent application.[842] Therefore, despite Mr. May's contention that FTI's findings were incorrect, it appears that ABC proceeded to act on them in an effort to create "more standardized, automated and objective process to drive decisions and processes."[843]

The 2016 adjustments included:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

However, [redacted].[845] Thus, despite the new algorithm, [redacted][846]

11.5.6 AmerisourceBergen's training efforts were ineffective due to an approach that was fragmented and inconsistent.

Despite maintaining ABC "provides mandatory training on its Diversion Control Program to sales associates, distribution center personnel, and other impacted personnel [and] … ABC regularly participates in collaborative efforts, including education and training with industry groups (such as HOMA, NADDI, ASIS, and NASCA),

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[841] *See* DC Enhancements 2016 at 4.

[842] *See generally* FTI Findings.

[843] *See* DC Enhancements 2016 at 5.

[844] *See* DC Enhancements 2016 at 6-7.

[845] *See* DC Enhancements 2016 at 7.

[846] *See, e.g.,* ABC Diversion Control Program, DCP SOP-12.2.30, § 5.4 (Jan. 1. 2007) [redacted] at ABDCMDL00003404.

manufacturing partners, and customer/buying groups,"[847] the company's approach to controlled substances training can be best described as "scattershot."

While ABC did attempt to provide training to the primary groups involved with SOM and controlled substances such as the sales teams, compliance managers, and even CSRA staff members, its training efforts were both fragmented and inconsistent. On the one hand, ABC, in the course of discovery in this case, produced several slide decks supposedly used as part of various training sessions.[848] On the other hand, no corresponding "sign-in" sheets or other records were located to support when specific sessions occurred and who attended, despite Mr. Zimmerman's 2014 inquiry to Cathy Marcum who responded that training was done "[a]nnually and it is documented on paper training logs."[849]

The result is that although Ed Hazewski testified that "everyone in the organization had some exposure to discussions and training that related to potential diversion issues,"[850] Stephen Mays could not recall if ABC required or maintained any records that would support Mr. Hazewski's contention.[851] Mr. Hazewski's contention was also contradicted by ABC's own employees.

For example, Julie Fuller, an ABC sales representative, stated that as an account manager, ABC only provided her general sales training, and did not provide any training or information on "(a) how to identify questionable pharmacy behavior like suspicious dispensing, sales, or prescription filling practices, (b) how to report concerns regarding those behaviors, or (c) how to ensure that account managers only signed up and maintained accounts with legitimate pharmacies."[852] This is consistent with what Mr. Zimmerman found in 2012 when he wrote to Mr. Hazewski that "[s]o far we have not met anyone from sales, VPs, RVPs, Director, Specialists, etc., that is aware of the OMP training, are you sure this has been rolled out and communicated?"[853] Later he wrote to Mr. Hazewski, "[w]e should work with Sales to ensure we know [who] is going to monitor and track … to make sure all sales folks go through the training."[854]

Later in 2014, Greg Madsen noted that neither the OMP policy nor the training were current, writing to Stephen Mays that:

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[847] *See* ABC, *AmerisourceBergen Diversion Control Program Overview*, 3 (Jan. 2016) ("Education and Training" section), ABDCMDL00303979 ["Diversion Control Program Overview"]

[848] *See, e.g.,* ABC Presentation, *Diversion Control Training Program for Sales Associates*, (Jul. 30 to Aug. 2, 2014) (The meeting was held at the MGM Grand Hotel in Las Vegas, Nevada), ABDCMDL00158342; ABC Presentation, *Diversion Control Program & OMP – General Awareness Training*, (Apr. 2016); ABC Presentation, *OMP Strategy for Retail Accounts – Low Dollar Controlled Substances High Risk,* (undated), ABDCMDL00282234; ABC Presentation, *Prescription Drug Diversion – Recognizing the Red Flags*, (undated), ABDCMDL00269475; ABC Presentation, *Diversion Control Program – DC OMP Training*, (May 2009), ABDCMDL00141716.

[849] *See* Email from C. Marcum to C. Zimmerman, *et al.*, Re: DCP/OMP Training Questions, (Feb. 27, 2014), ABDCMDL00277674.

[850] *See* E. Hazewski Deposition at 44:16-19.

[851] *See* S. Mays Deposition at 239:19-21.

[852] *See* Declaration of Julie Fuller ¶9 (Jan. 26, 2019).

[853] *See* Email from C. Zimmerman to E. Hazewski, *et al.*, Fwd: CSRA Training – Questions, (Dec. 20, 2012, 11:17 AM), ABDCMDL00269150.

[854] *See* Email from C. Zimmerman to E. Hazewski, et al*.*, Re: CSRA Training – Questions, (Dec. 20, 2012, 11:17 AM), ABDCMDL00269150.

> I'm not complaining or trying to cause a headache. Probably not that big of a deal but the training and the policy have not been updated since 2008/09 as far as I know. Heck, I could be way off base or not up to date myself. DC's have developed their own training in my region for general OMP training at the DC level and RPIC training. OMP training is posted on the CSRA web site but it is not in sync with what is required at the DC level and the training and policy are in based on old star system methods. Many requests have been made to Ed (by me, Cathy and Tony) and I haven't seen anything yet.[855]

Mr. Mays simply responded, "Ok, it will get updated at some point soon."[856]

However, "soon" for Amerisource Bergen meant <u>two years</u> later. A string of emails authored in January 2016 show that despite expressing a recognition that OMP training needs to be conducted annually, ABC persisted in using an OMP training module described by various different employees as "ancient history," and "sorely outdated."[857] Furthermore, in the absence of an established CSRA program, the distribution centers created their own OMP training "which was all over the map" in an effort to fill the gap.[858]

Contributing to this fragmented and inconsistent approach was the fact that CSRA had no formal, documented training process for controlled substances compliance that was located. At a minimum, this training process should have detailed the mandatory training curriculum, the maintenance of training records, and how completion is monitored. However, it does not appear to exist in either the Diversion Control Program or the CSRA policies and procedures pertaining to controlled substances.[859] Therefore, ABC's claims of mandatory training in the Diversion Control Program Overview could not be verified by me.[860]

CSRA also did not have specific staff members directly responsible for implementing, overseeing and monitoring training. Instead CSRA apparently opted for making the entire team responsible for training.[861] As a result, FTI concluded that:

> For the most part, CSRA team members do not receive much in the way of formal training and instead are, in the best case, provided informal training by being paired with a more experienced resource for a brief onboarding period. As a result, some CSRA personnel feel overwhelmed by the volume of activities they are required to perform, the administrative demands of their position and the lack of direction that they are provided.[862]

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[855] *See* Email from G. Madsen to S. Mays, RE: DCP/OMP Training Questions, (Feb. 27, 2014, 2:10 PM), ABDCMDL00291500.

[856] *See* Email form S. Mays to G. Madsen, RE: DCP/OMP Training Questions, (Feb. 27, 2014, 2:10 PM), ABDCMDL00291500.

[857] *See* Email from E. Cherveny to N. Seckinger, RE: OMP-General Training for all Associates (Jan. 15, 2016), ABDCMDL00151814.

[858] *See* Email from E. Cherveny to N. Seckinger, RE: OMP-General Training for all Associates (Jan. 15, 2016), ABDCMDL00151814.

[859] *See* Appendix E, Figure 2.

[860] *See* Diversion Control Program Overview at 3 ("Education and Training" section).

[861] *See* S. Mays Deposition at 239:6-7.

[862] *See* FTI Narrative at 8.

Consequently, FTI concluded that "CSRA needs to standardize, improve and/or develop more specific training by discipline and job function, [and] [t]he training also needs to address regulatory compliance activities and help CSRA personnel learn to view' their activities through a risk management lens."[863]

Although David May disagreed with FTI's conclusion saying, "it was my view that, generally speaking, CSRA team members were receiving training that was sufficient for them,"[864] a March 2016 email from Greg Madsen, CSRA Director for the West Region debunks that conclusion. Mr. Madsen wrote to an ABC Distribution Center that while "we want your lead clerk to be fluent in all key areas and be able to take over for you while you are out of the office," he noted that "[t]here is **no one set training regime for the lead clerk**."[865]

At some point after FTI's report, it appears that CSRA created an informal CSRA Training Committee. The first references to the Committee, however, do not appear until June 2016 indicating that it was a late addition to ABC's controlled substances compliance efforts.[866] With the appearance of the CSRA Training Committee in June 2016 also comes the first reference to a controlled substances course list.[867] However, the course list from June 2016 shows that many of the CSRA training programs, beyond just controlled substances, either were not being addressed or were incomplete.[868]

For any compliance function, even a foundational one, the failure to address these basic training issues represent at best simple sloppiness. In the context of a controlled substances compliance program, they are enough to conclude that by failing to adequately train its employees, ABC was not maintaining an effective anti-diversion program.

11.5.7 ABC's failure to implement a formal corrective action program contributed to the company's continued ineffective controlled substances compliance program.

Although ABC made periodic changes to its controlled substances compliance program during the review period, there is little evidence to suggest that these changes originated through an internal corrective action program. Rather, the impetus for most of the significant program changes come from external sources - the DEA and FTI.

It also is clear that ABC did not have a robust internal audit function that addressed controlled substances. In 2009, Mr. Hazewski sent a formal memorandum to Mr. Zimmerman discussing the findings from an audit of the

863 *Id.*

864 *See* D. May Deposition at 128:17-20.

865 *See* Email G. Madsen to G. Guevara and P. Neipp, FW: Lead Clerk Training, (Mar. 1, 2016) (emphasis added), ABDCMDL00311966.

866 *See* Email from F. Duncan to G. Crowley, *et al.*, CSRA Training Committee Weekly Meeting – Notes, Updated Course List & Actions attached, (Jun. 22, 2016), ABDCMDL00303935.

867 *See* Email from F. Duncan to G. Crowley, *et al.*, CSRA Training Committee Weekly Meeting – Notes, Updated Course List & Actions attached, (Jun. 22, 2016), ABDCMDL00303935.

868 *See* CSRA Training Program Overview Spreadsheet, (undated) (Entries date to early June 2016), ABDCMDL00303937; *see also*, K. Kreutzer email to J. Sutherland, *et al.*, FW: CSRA Training Committee – OMP Program Follow-up, (Jul. 20, 2016), ABDCMDL00303977.

OMP program conducted by Michael Mapes, an ex-DEA employee.[869] To conduct his "audits," Mr. Mapes utilized a checklist that cataloged the requirements from CSRA's diversion control policies and procedures and noted "compliant" or "not compliant."[870] However, the checklist's format does not allow the auditor to add details, explanations or even the samples that were pulled to support the compliant/not compliant designation.

Although billed as an "audit," the Mapes Checklist is merely a quality control device. It certainly is not an "audit" that is designed to detect and highlight issues to be corrected. For example, in the case of CSRA Form 590, the checklist only inquires whether the Form 590 has been completed for all new retail pharmacy applicants and whether the 590c was being used by CSRA to verify responses.[871] Despite these questions being asked on an annual review of CSRA files, it appears that this "audit" program failed to uncover the fact that CSRA frequently was failing to require completed Form 590s until more than 3,200 customers were impacted. Nor did this "audit program" take issue with the fact that almost 12 months later, ABC was struggling to complete remediation on 10% of the outliers.

11.6 Accountability - Consistent Enforcement

11.6.1 AmerisourceBergen does not enforce the standards of the program, and thus there is no real accountability for the program's lack of effectiveness.

AmerisourceBergen did not take steps to "remove" those individuals from positions of substantial authority for controlled substances compliance even though their actions and failures to act helped render the controlled substances compliance program ineffective to detect and prevent diversion. As a result, these individuals have yet to be held accountable for their roles in the controlled substances compliance program's failure:

1. **Christopher Zimmerman –** Although recently removed from his position as ABC's Chief Compliance Officer, Mr. Zimmerman remains in control of CSRA and thus AmerisourceBergen's anti-diversion efforts.
2. **Stephen Mays –** The scope of Mr. Mays role within ABC's diversion control program has varied over the years, but as head of ABC's Pharmaceutical Distribution and Global Sourcing Group, he retains substantial sway over the implementation of the program.
3. **David May –** As the current head of Security and Diversion Control, Mr. May continues to have direct day-to-day oversight of ABC's program.

The same lack of accountability can be seen with ABC's sales representatives, As Nathan Elkins testified, no sales representative who worked for him was ever fired for not reporting a suspicious order.[872]

[869] *See* Memorandum from E. Hawzewski to C. Zimmerman, *OMP Audit*, (Dec. 17, 2009).

[870] *See* AmerisourceBergen, *Diversion Control Program Audit Checklist*, (Dec. 14, 2007) (The checklist notes that it is for internal corporate audits).

[871] *See id.* at 3, Questions 1 and 3.

[872] *See* N. Elkins Deposition at 158:8-15.

By failing to hold individuals accountable for the controlled substances program's established lack of effectiveness or for not complying with ABC's policies and procedures, AmerisourceBergen's corporate compliance program was mere words on paper that professed to hold culpable individuals accountable.

12 CVS Health Inc.

12.1 Background

CVS Health, Inc. ("CVS") began in 1963 as a single store selling health and beauty products in Lowell, Massachusetts by the brothers Goldstein (Stanley and Sidney) and their partner Ralph Hoagland.[873] At the end of 2017, CVS, which stands for Consumer Value Stores, had more than 9,800 pharmacies in the U.S., Puerto Rico and Brazil employing more than 246,000 people in the U.S,[874] and net annual revenues of $184.8 billion.[875] Much of CVS' growth was accomplished by a series of strategic mergers including Caremark Rx, Inc. (PBM services) in 2007, Omnicare (pharmacies in long-term care facilities) in 2015, and Aetna (health insurance)in 2018.[876]

From 2006 to 2014, CVS distributed opioids (hydrocodone combination products or HCPs) from two distribution centers to its retail stores organized under the CVS Pharmacy, Inc. umbrella.[877] The primary controlled substances distribution center in this case was CVS Indiana L.L.C. located in Indianapolis, Indiana and an ancillary center, CVS Rx Services LLC., located in Chemung, New York. With the reclassification of hydrocodone combination products from Schedule III to Schedule II in 2014,[878] CVS ceased the internal distribution of any opioid products to its retail locations at the end of September that year.[879]

12.2 Executive Summary

CVS likes to describe itself as "a health care innovation company helping people on their path to better health … transforming the consumer health care experience and helping to foster healthier communities."[880] The

[873] *See* CVS HEALTH, *History*, https://cvshealth.com/about/company-history (last visited Feb. 17, 2019).

[874] *See* CVS HEALTH, *CVS Health at a Glance*, https://cvshealth.com/about/facts-and-company-information (last visited Feb. 17, 2019).

[875] *See* CVS HEALTH, *Financial Highlights*, https://investors.cvshealth.com/investors/2017-in-review/default.aspx (last visited Feb. 17, 2019).

[876] *See* CVS HEALTH, *History*, https://cvshealth.com/about/company-history (last visited Feb. 17, 2019).

[877] For Schedule II opioids, CVS utilized other distributors including primarily the G1 distributors.

[878] *See* 79 Fed. Reg. 49661 (Aug. 22, 2014).

[879] *See* Email from D. Coakley, RE: Hydro Transition Meeting Questions, (Sep. 23, 2014) (referencing September 26, 2014 as the last shipment date for HCPs), CVS-MDLT1-000002195.

[880] *See* CVS HEALTH, *Investor Story,* https://investors.cvshealth.com/investors/investor-story/default.aspx (last visited Feb. 17, 2019).

company's compliance actions, however, suggest that CVS does not view compliance as an important part of its efforts to transform the health care experience.

Overall, from 2008 to 2018, CVS has settled six major cases with the Justice Department, the HHS OIG, and the DEA. Half of the settlements involved health care fraud issues, including federal false claims allegations.[881] The other half involved repeated violations of the Controlled Substances Act and its accompanying regulations.[882] This is an exceedingly poor compliance record for one of the largest retail pharmacy chains in the U.S.

Coupled with its poor compliance record, CVS simply considered distribution center compliance with the controlled substances requirements to be an afterthought, and as a result, the DC anti-diversion program did not impact CVS' business or cultural equations in a meaningful way.

This lack of compliance prioritization and commitment manifested itself in four key respects:

- **Dual Roles**: Even though CVS simultaneously occupied both the dispenser and distributor roles for controlled substances in the "closed loop" system, CVS made little effort to incorporate its own pharmacy dispensing data within its SOM program.[883] When CVS did make an effort to do so, the data used often was incomplete or "stale." The fact that CVS did not effectively do so was a missed opportunity to improve its program significantly.

- **Corporate Entity Structure**: The CVS organization has evolved an extremely complicated and compartmentalized corporate entity structure that is akin to the entity structure typically seen in Chinese or Japanese pharmaceutical companies. CVS appears to use that structure to avoid taking responsibility for obligations it wishes to avoid. In the case of the distribution center anti-diversion program, this structure, which created isolation and fragmentation, impeded any improvement efforts. As a result, CVS essentially shunned the program and avoided meeting its obligations in a forthright manner.

- **Failure to Adequately Prioritize Controlled Substances Compliance:** CVS prioritized revenue generation and preventing any disruption to the retail pharmacies' ability to fill prescriptions over any

[881] *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Caremark Corporation (Mar. 14, 2008) https://oig.hhs.gov/fraud/cia/agreements/cvs_cia_executed.pdf; Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Caremark Corporation (Mar. 25, 2014), https://oig hhs.gov/fraud/cia/agreements/CVS_Caremark_03252014.pdf; Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Health Corporation (Oct. 11, 2016), https://oig.hhs.gov/fraud/cia/agreements/CVS_Health_Corporation_10112016.pdf.

[882] Press Release CVS/pharmacy, *Lapse in controls of PSE sales in certain CVS/pharmacy stores in 2007 and 2008 relates to electronic monitoring system flaw that has been corrected Settlement amount fully reserved and previously disclosed; should have no further effect on company's financial results,* (Oct. 4, 2010), https://cvshealth.com/newsroom/press-releases/cvspharmacy-announces-agreements-us-drug-enforcement-administration-and-us-attorneys-offices; Press Release, U.S. Dep.'t of Justice, Drug Enforcement Admin., CVS To Pay $11 Million To Settle Civil Penalty Claims Involving Violations Of Controlled Substances Act, (Apr. 3, 2013), https://www.dea.gov/press-releases/2013/04/03/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-0; Press Release, U.S. Dep.'t of Justice, Drug Enforcement Admin., CVS Pharmacy, Inc. to pay $1.5 million to settle Civil Penalty Claims for violation so [sic.] the Controlled Substance Act, (Jun. 28, 2018), https://www.dea.gov/press-releases/2018/06/28/cvs-pharmacy-inc-pay-15-million-settle-civil-penalty-claims-violation-so.

[883] This is the same information that CVS has refused repeatedly to provide with the G1 distributors.

distribution center anti-diversion efforts. Throughout the period, CVS allowed the controlled substance program to be severely under-resourced both in terms of total headcount and in terms of the skills and abilities of its dedicated team members (e.g., Messrs. Devlin, Mortelitti, and Miliken, etc.). Even when notified of system deficits that negatively impacted the ability of its SOM program to function, CVS failed to undertake timely and comprehensive corrective actions.

- **Tolerance of Misstatements and Errors:** Perhaps the most troubling aspect of CVS' lack of commitment, is the fact that the company allowed multiple gaps and inconsistencies in its anti-diversion program to persist unabated for periods of months or even years with no documented corrective action plan. CVS also seemed oddly comfortable allowing its employees to make obviously incorrect statements to federal regulatory authorities. This speaks to a culture where revenue generation and preventing disruption to the retail pharmacies were the valued company objectives - not compliance.

Applying the compliance maturity and program effectiveness model here, the CVS program is difficult to classify as being at the foundational level, and if the model had a remedial level, I would place the CVS program there.

12.3 Impact

The impact of CVS' failure to maintain a credible anti-diversion program is clear. During the relevant period, CVS reported no suspicious orders to the DEA regarding any of its pharmacies in Cuyahoga or Summit Counties.[884] In fact the Item Review Report ("IRR") Recap Reports from January 2011 to June 2012 show that only <u>one</u> flagged order of hydrocodone was selected for additional due diligence in Cuyahoga and Summit Counties during that eighteen-month period.[885] During this same period of time, the report shows months, where not one (i.e., zero) flagged hydrocodone order nationwide was investigated further after being listed on the IRR Report.[886] In a similar vein, the IRR Recap Report for the <u>ten-month period</u> spanning February 6, 2013, to December 30, 2013, identified only <u>one</u> hydrocodone order in Cuyahoga or Summit counties that was investigated further.[887]

<u>Indianapolis Distribution Center</u>

In November 2013, the DEA notified the head of the Indianapolis distribution center ("DC"), Mark Nicastro of two stores that clearly were suspicious, but to which CVS continued shipping hydrocodone unabated. Despite this CVS claimed that the company had an effective anti-diversion and suspicious order monitoring program. To quote the DEA, these stores were:

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[884] *See* CVS RX Services, Inc.'s and CVS Indiana L.L.C.'s Objections and Responses to Plaintiffs' (First) Combined Discovery Requests to National Retail Pharmacy Defendants, Requests Nos. 3-4.

[885] *See* IRR Recap Report, (Jan. 2011 to Jun. 2012), CVS-MDLT1-000009740.

[886] *See id.*

[887] *See* A. Burtner Deposition at 485:20-487:1; IRR Recap Report, (Feb. 6, 2013-Dec. 30, 2013), CVS-MDLT1-000010268.

> CVS Store# 06880/ DEA # AH9157137 ordered 1,888,600 dosage units of Hydrocodone (Drug Code 9193) between January 1, 2012, through October 2013. Of which 1,766,000 tablets of Hydrocodone were shipped from your facility. This pharmacy is located in Vincennes, IN with a population of approximately 18,000.
>
> Additionally, CVS Store# 6757/DEA# AH2693376 located in Columbus, IN ordered a total of 2,012,400 tablets of which your facility provided 1,756,300 tablets from January 1, 2012, through October of 2013. The population of Columbus, IN is approximately 45,000.[888]

12.4 Company Commitment – Compliance Culture, Organization & Resources

12.4.1 CVS' compliance record is indicative of a company that has a poor commitment to compliance.

CVS, as noted above, describes itself as "a health care innovation company helping people on their path to better health … transforming the consumer health care experience and helping to foster healthier communities."[889] However, the company's compliance history reveals a company that has entered into a series of Corporate Integrity Agreements, 2008 (CVS Caremark),[890] 2014 (CVS Caremark),[891] 2016 (CVS Health Corporation)[892] with the OIG for various healthcare offenses not related to controlled substances. Thus, the Justice Department has taken issue with CVS' commitment to compliance on three separate occasions.

CVS's controlled substances compliance record is also checkered. The company has settled three sets of major allegations involving controlled substances since 2009.[893] One case involved the excessive sales of pseudoephedrine ("PSE") by CVS stores in California and Nevada in 2007 and 2008.[894] In exchange for a non-prosecution agreement and civil settlement, CVS paid $77.6 million in civil penalties and profit forfeitures.[895]

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[888] *See* Email from D. Gillen to M. Nicastro, CVS Store #06880 & 6757, (Nov. 25, 2013), CVS-MDLT1-000076135.

[889] *See* CVS HEALTH, *Investor Story,* https://investors.cvshealth.com/investors/investor-story/default.aspx (last visited Feb. 17, 2019).

[890] *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Caremark Corporation (Mar. 14, 2008) https://oig.hhs.gov/fraud/cia/agreements/cvs_cia_executed.pdf .

[891] *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Caremark Corporation (Mar. 25, 2014), https://oig hhs.gov/fraud/cia/agreements/CVS_Caremark_03252014.pdf .

[892] *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Health Corporation (Oct. 11, 2016), https://oig.hhs.gov/fraud/cia/agreements/CVS_Health_Corporation_10112016.pdf .

[893] CVS has settled numerous smaller cases with the DEA involving its retail pharmacy stores in Massachusetts (2015 and 2016, CVS-MDLT1-000099702 and 000060872), Texas (2014 and 2015, CVS-MDLT1-000060907 and 000060915), and Maryland (2016, CVS-MDLT1-000060805).

[894] *See* Press Release CVS/pharmacy, *Lapse in controls of PSE sales in certain CVS/pharmacy stores in 2007 and 2008 relates to electronic monitoring system flaw that has been corrected Settlement amount fully reserved and previously disclosed; should have no further effect on company's financial results,* (Oct. 4, 2010), https://cvshealth.com/newsroom/press-releases/cvspharmacy-announces-agreements-us-drug-enforcement-administration-and-us-attorneys-offices.

[895] *Id.*

Another case in 2013 ended when CVS agreed to pay $11 million in civil monetary penalties to resolve recordkeeping violations involving CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy, LLC.[896] The DEA alleged that from October 2005 to October 2011, CVS violated a number of controlled substances recording keeping requirements including creating and maintaining "dummy" DEA registrations for prescribers and filling prescriptions for physicians lacking current or valid DEA registration numbers.

CVS, in June 2018, once more settled allegations of controlled substances violations by its pharmacies in Nassau and Suffolk counties, New York.[897] Apparently, these CVS stores failed to report thefts and losses of various controlled substances including hydrocodone.[898] CVS Pharmacy, Inc. agreed to pay $1.5 million in civil penalties to resolve the matter.[899]

12.4.2 CVS' penchant for complexity and compartmentalization resulted in a confusing and ineffective organizational approach to controlled substances compliance.

In general, CVS' view of compliance simply does not enter its business or cultural equation in a meaningful way. CVS' actions demonstrated this in three distinct, but interrelated areas:

- Its corporate entity structure,
- The assigning responsibility for controlled substances compliance, and
- Its failure to integrate its controlled substances and corporate compliance teams.

A. CVS Entity Structure

CVS Health, the corporate parent of all CVS operations, has created an extraordinarily complicated and compartmentalized entity structure. For example, CVS Pharmacy, Inc., a subsidiary of CVS Health, Inc., "owns, either directly or indirectly, all of the CVS retail pharmacies."[900] CVS also operates two separately incorporated controlled substances distribution centers relevant to this report: CVS Indiana L.L.C. located in Indianapolis, Indiana and CVS Rx Services, Inc. located in Chemung, New York. These entities were in turn owned by CVS Pharmacy, Inc.[901]

From an operational perspective, such an entity structure creates confusion and interferes with business operations and processes that span multiple corporate entities. The entity structure does this by obfuscating

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[896] *See* Press Release, U.S. Dep.'t of Justice, Drug Enforcement Admin., CVS To Pay $11 Million To Settle Civil Penalty Claims Involving Violations Of Controlled Substances Act, (Apr. 3, 2013), https://www.dea.gov/press-releases/2013/04/03/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-0

[897] *See* Press Release, U.S. Dep.'t of Justice, Drug Enforcement Admin., CVS Pharmacy, Inc. to pay $1.5 million to settle Civil Penalty Claims for violation so [sic.] the Controlled Substance Act, (Jun. 28, 2018), https://www.dea.gov/press-releases/2018/06/28/cvs-pharmacy-inc-pay-15-million-settle-civil-penalty-claims-violation-so.

[898] *Id.*

[899] *Id.*

[900] *See* Mark Vernazza Deposition, 53:23-54:1 (Nov. 20, 2018) (Mr. Venazza is Senior Legal Counsel for CVS Pharmacy, Inc. and was the 30(b)(6) witness for the two CVS distribution centers in this case).

[901] *See* Figure 1 *infra* Appendix F.

where responsibility and authority for various operations and processes reside. As a result, corporate inertia sets in as employees do not know how to get things accomplished.

CVS further compounded these issues and challenges resulting from a compartmentalized corporate entity structure by not creating the entities that were truly separate. For example, if the Indianapolis and Chemung distribution centers were truly separate entities, then one would expect to see internal contracts or service level agreements ("SLAs") between the distribution centers and CVS Pharmacy, Inc. setting out the distribution expectations for the individual pharmacies. Likewise, since CVS Pharmacy, Inc. owned and controlled the pharmacy ordering system, there should be SLAs between CVS Pharmacy, Inc. and the distribution centers, which depend on that system to ensure timely order fulfillment.[902] However, CVS did not have any such contracts, nor were the pharmacies required to pay for the products or the delivery services provided by Indianapolis and Chemung.[903] Thus, ownership of the distribution process and the underlying order system were not clear cut. These are signs of poor corporate governance.

B. CVS Controlled Substances "Team"

This penchant for complexity and compartmentalization that is seen with the entity structure carried over into the organizational design of the controlled substances program. Rather than take a straight-forward approach of designating a "high-level" individual or group with sole responsibility for controlled substances compliance, CVS opted for a convoluted structure with diffuse responsibility across functional lines and corporate entities. This resulted in a controlled substances compliance "team structure" that lacked both accountability and effectiveness.

This confusion caused by CVS' cumbersome, compartmentalized approach was readily apparent when viewed in the context of which department "owned" the SOM process. Throughout the period, "ownership" of the SOM program involved two separate functional lines within CVS: (a) Logistics and (b) Loss Prevention ("LP"). From 2006 to 2012-2013, "ownership" of the SOM program resided under Loss Prevention, which was a department located at CVS Headquarters in Woonsocket, Rhode Island.[904] Sometime between 2012 and 2013, there was consensus that the Logistics Planning Department, a subset of the Logistics Department, took over "ownership" of the SOM program.[905]

However, there was some discrepancy as to precisely when the transfer from LP to Logistics took place. An email from Mark Nicastro in August 2013 suggested that Logistics took over well before August 2013: "My understanding is Logistics owns the process so either Dean [Vanelli] or I have it."[906] Dean Vanelli, Senior

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[902] *Id.* at 48:2-6.

[903] *Id.* at 48:17 to 52:2.

[904] *See* Ronald Link Deposition, 19:23 to 20:1 (Dec. 11, 2018), *but see* Email from M. Nicastro to R. Link and W. Jusko, SOM Update (Aug. 18, 2013), CVS-MDLT1-000012363; Email from D. Vanelli to R. Link, *et al.,* FW 2013 Logistics Planning Initiatives (Jan. 9. 2014), CVS-MDLT1-000000459; CVS Logistics Planning Organizational Chart (Jan. 1, 2014) CVS-MDLT1-000037885.

[905] *See id.* at 19:21-22; *see also* Dean Vanelli Deposition, 18:23-19:3; 23:7-19 (Jan. 16, 2019).

[906] *See* Email from M. Nicastro to R. Link and W. Jusko, SOM Update (Aug. 18, 2013), CVS-MDLT1-000012363; *but cf.* R. Link, Deposition at 19:16-22 (stating the transition occurred in 2012).

Director of Logistics Planning, in a 2014 email discussing his department's 2013 initiatives stated that he assumed ownership of the SOM program.[907]

Similar confusion surrounded Amy Propatier's role in the SOM Program. Reference to Mrs. Propatier's SOM role can be found in the 2011 version of the CVS DEA SOP Manual, where it named her as "CVS DEA Compliance Coordinator."[908] The same section also referenced Frank Devlin as the Director of Logistics Loss Prevention.[909] Ronald Link, Vice President of Logistics to whom Logistics Planning reported, stated that while he did not have contact with Mrs. Propatier, he knew she was the CVS "DEA Coordinator."[910] According to Mrs. Propatier, "her duties" as DEA Coordinator involved filing ARCOS reports and updating the DEA SOP Manual.[911] Consequently, as Mrs. Propatier stated, the DEA Coordinator title was "a title for reference in SOPs," and therefore was not included in her personnel records."[912]

From 2006 to 2014, Mrs. Propatier's official duties were "hazardous materials specialist and logistics liaison" that, as of 2008, evolved into a "logistics Rx services manager"[913] within the Logistics Planning department. Dean Vanelli, Senior Director of Logistics Planning, claimed "[a]t no time did Amy have ownership for any DEA compliance … with the exception of she was responsible for filing ARCOS reporting."[914] Mr. Vanelli's statement is supported by Logistics Planning organizational charts.[915]

C. Integrating the Controlled Substances and Corporate Compliance Teams

Since at least 2007, there has been a Chief Compliance Officer of CVS Health, Inc., and before that CVS Caremark Corporation. From 2007 to the present, three people have occupied that post:

- Diane Nobles, Senior Vice President, Compliance & Integrity from 2007 to 2010.[916]
- John Buckley, Senior Vice President, Chief Compliance Officer from 2011 to 2015.[917]
- David Falkowski, current Senior Vice President and Chief Compliance Officer for CVS Health, Inc.[918]

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[907] *See* Email from D. Vanelli to R. Link, *et al.,* FW 2013 Logistics Planning Initiatives (Jan. 9. 2014), CVS-MDLT1-000000459.

[908] *See* CVS Distribution Center, *Controlled Drug – DEA Standard Operating Procedures Manual RX-01*, X-8, § E.3 (Nov. 8, 2011), CVS-MDLT1-000008506 ["RX-01(11/11)"].

[909] *Id.*

[910] *See* R. Link Deposition at 21:5-20, 24:1-5.

[911] *See* Amy Propatier Deposition 80:17 -81:2; 103:7-15; 104:5-120:21 (Nov. 29, 2018) (inquiring about any other duties she might have performed).

[912] *See id.* at 79:24 to 80:2, 81:18 -82:1.

[913] *See id.* at 17:10-19.

[914] *See* D. Vanelli Deposition at 50:21-24.

[915] *See* CVS Logistics Planning Organizational Chart (Apr. 15, 2013); CVS Logistics Planning Organizational Chart (Jan. 1, 2014).

[916] Diane Nobles LinkedIn Profile, https://www.linkedin.com/in/dbnobles/ (last accessed Feb. 12, 2019) (Prior to joining Walgreens, Ms. Nobles left CVS to become CCO of Walgreens from 2013-2016).

[917] *See* John Buckley LinkedIn Profile, https://www.linkedin.com/in/jmbuckleycco/, (last accessed Feb. 26, 2019).

[918] *See* David Falkowski LinkedInProfile, https://www.linkedin.com/in/david-f-45037626/ (last accessed Feb. 26, 2019).

However, no evidence was presented suggesting a linkage, much less integration, between the two compliance teams. This is even more troubling because from 2008 to the present, CVS was the subject of three separate Corporate Integrity Agreements, all mandating enhanced attention to all facets of compliance.[919] This, however, did not seem to include controlled substances compliance.

This failure by CVS strongly suggests that CVS focused little on controlled substances. Had CVS done so, it would have helped the anti-diversion team highlight critical issues and secure additional management support. By not doing so, CVS missed an opportunity to move towards a credible anti-diversion program. It also demonstrated a lack of company commitment to meeting its controlled substances obligations.

12.4.3 CVS also failed to properly resource its controlled substances compliance efforts throughout the period.

CVS's extraordinary fragmentation of responsibilities for the anti-diversion program also negatively impacted the resourcing for the controlled substances compliance efforts. In short, throughout the review period, the controlled substances "team" was staffed at such a low level that it was ineffective.

Starting in the 2009 timeframe, CVS centralized the review of all Inventory Review Reports ("IRRs") at a single distribution center in Lumberton, New Jersey under John Mortelliti, Loss Prevention Manager for the Lumberton Distribution Center and the mid-Atlantic region.[920] Thus from 2009 to March 2011, CVS had only one person doing the daily review of the IRRs for the entire country.[921] As a Loss Prevention Manager, Mr. Mortelliti had no prior experience with suspicious order monitoring and did not recall any training he received.[922] The same was true for Frank Devlin, Director of Loss Prevention and Mr. Mortelliti's superior.[923]

When the finalized version of the SOM program was inserted into the DEA SOP manual in August 2010, CVS planned to have each distribution center reviewing its own IRRs.[924] This change could have provided 11 FTEs to help handle the volume of IRR reports.[925] However, the change was never made, and the IRR reviews

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[919] *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Caremark Corporation (Mar. 14, 2008) https://oig.hhs.gov/fraud/cia/agreements/cvs_cia_executed.pdf ; Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Caremark Corporation (Mar. 25, 2014), https://oig hhs.gov/fraud/cia/agreements/CVS_Caremark_03252014.pdf ; Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and CVS Health Corporation (Oct. 11, 2016), https://oig.hhs.gov/fraud/cia/agreements/CVS_Health_Corporation_10112016.pdf .

[920] *See* Henry John Mortelliti, III Deposition, 18:10-19:1 and19:6-12, (Jan. 23, 2019).

[921] *Id.*; *see also* Email from J. Mortelliti to E. Demetrius RE: IRR/SOM Retunement BSR_LOG_61148 (Mar. 14, 2011), CVS-MDLT1-000057759.

[922] *See* J. Mortelliti Deposition at 19:13-22:5; 46:20-47:10.

[923] *See* F. Devlin Deposition at 168:12-169:4.

[924] *See* CVS Distribution Center, *Controlled Drug – DEA Standard Operating Procedures Manual,* VIII-7, § D.4 (Aug. 25, 2010), CVS-MDLT1-000088956 at CVS-MDLT1-000088957 ["RX-01(2010)"]; CVS Presentation, *Suspicious Order Monitoring for PSE/Control Drugs: Summary of Key Concepts and Procedures*, 7 (Aug. 27, 2010), CVS-MDLT1-000075300 ["DEA Speaking Points"];

[925] *See* Email from C. Tulley to P. Hinkle, *et al.*, RE: Recap progress made, (Nov. 11, 2012), CVS-MDLT1-000055834.

continued to be done by only a few individuals at any one time.[926] CVS claims the reason for not pushing IRR review into the individual distributions centers was "review consistency" and operational efficiency.[927] In March 2011, the IRR review process was transferred from Lumberton to Knoxville under the control of Pam Hinkle.[928] Upon the move to Knoxville, Ms. Hinkle ultimately gained two Loss Prevention Analysts assigned to the SOM program.[929]

The IRR workload with CVS was substantial as IRRs are generated daily for each distribution center.[930] Therefore, in between 2009 and 2010, that meant at least 10 reports per day were generated.[931] A single sample IRR for the Indianapolis DC on November 30, 2010 contained 355 entries (71 pages x 5 lines per page).[932] While it is unclear whether this was a "typical" IRR,[933] even if this IRR were halved, that translates into approximately 1,550 orders per day or approximately 387,500 orders per year across all distribution centers.[934]

In the summer of 2012, Aaron Burtner, SOM Manager, conducted a series of time studies to outline his average day.[935] The results of those time studies revealed that CVS employees were doing, at best, a cursory review of the daily IRRs.[936] Based on the number of daily orders on the IRR and Mr. Burtner's time studies, the staffing level provided by CVS to review "flagged" orders was not sufficient to accomplish the task of conducting meaningful due diligence on orders listed on the IRR.

12.4.4 CVS's tolerance of program documentation that was either non-existent, incomplete or inaccurate is indicative of a company with a poor compliance culture.

Throughout the review period, the CVS team operated with non-existent, incomplete or simply inaccurate program documentation. While it is not unexpected for a compliance program's documentation to be out of sync or inconsistent with current operational practices, normally, these periods are short-lived and as the result of non-routine events, such as a merger, department reorganization, changes in personnel titles and reporting lines, etc. It also is no surprise that the frequency of these types of events correlates directly with the size and complexity of the organization. When these situations occur, the organization committed to compliance will

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[926] *See* Pamela Hinkle Deposition, 38:4 to 39:20 (Jan. 24, 2019)

[927] *See* E mail from A. Burtner to C. Tulley and P. Hinkle, RE: Recap progress made, (Nov. 11, 2012), CVS-MDLT1-000055834; *see also* F. Devlin Deposition at 161:19.

[928] *See* Email from J. Mortelliti to E. Demetrius, *et al.*, RE: IRR/SOM Retunement BSR_LOG_61148 (Mar. 14, 2011), CVS-MDLT1-000057759; *see also* P. Hinkle Deposition at 26:4-27:8; RX-01(11/11) at VIII-7, § D.4.

[929] *See* P. Hinkle Deposition, 33:7-35:11.

[930] *See* J. Mortelliti Deposition 40:7-9.

[931] *Id.* at 39:9-12 to 40:3-6.

[932] *See* Item Review Report, BIP006A (Nov. 30, 2010), CVS-MDLT1-000100775.

[933] *See* J. Mortelliti at 38:22 to 39:1.

[934] The formula is 31 pages x 5 items per page x 10 distribution centers = 1,550. Annualized the formula is 1,550 x 5 days per week x 50 weeks per year (assuming holidays and 1-week preventative maintenance shut down) = 387,500

[935] *See* A. Burtner Deposition at 340:16-23.

[936] *Id.* at 341:19 to 371:18 (including exhibits 411-418); *see also* Discussion *infra.*

recognize the gaps or inconsistencies and create a plan to remedy them in a timely manner (e.g., a corrective action plan).

Therefore, it is outside the norms of good corporate governance, as well as a symptom of an organization's poor compliance culture, for an organization to allow multiple gaps and inconsistencies to persist unabated for periods of months or even years with no corrective action plan. This was the case with CVS.

As previously discussed, the designation of Amy Propatier as the "CVS DEA Compliance Coordinator," an artificial position in the DEA SOP manual was an example of CVS's failure to ensure its anti-diversion program's documentation matched current practices.[937] By providing the document naming Mrs. Propatier as the CVS DEA Compliance Coordinator, CVS misrepresented its program to a federal regulatory agency.

Likewise, in 2010 when finalizing the SOM segment of the DEA SOP manual, CVS developed and formally approved a set of speaking points "for the DEA agents if they come … and question suspicious monitoring."[938] Although acknowledging that the slide deck could be shared with the DEA, Mr. Mortelliti, nevertheless, cautioned: "Please be sure your team understands it before presenting, **so it doesn't look like a prop instead of a tool**."[939]

The DEA Speaking Points slide deck stated "DC Rx – Review Report (IRR) Daily and determine whether variances are within acceptable ranges."[940] According to Frank Devlin, "DC Rx" is a reference to the distribution center pharmacy.[941] However, the DEA SOP manual issued two days before the date of the DEA Speaking Points slide deck stated: "Currently the Item Review Report (IRR) for control drugs is being reviewed at a central location in NJ. During the month of September 2010, the report will be transitioned to each pharmacy DC …"[942] This never occurred, and the DEA SOP manual in November 2011 reflected this situation stating "Currently the Item Review Report (IRR) for control drugs is being reviewed at a central location in Knoxville, TN."[943] Thus, the DEA Speaking Points misrepresented the CVS SOM program when it was created and approved to be given to the DEA.

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937 *See* Discussion and notes *infra*

938 *See* Email from J. Mortelliti to M. Jamagin, FW: DEA Speaking Points (Sept. 1, 2010), CVS-MDLT1-000075299.

939 *Id.* (emphasis added).

940 *See* DEA Speaking Points at 7.

941 *See* F. Devlin Deposition at 139:2-5

942 *See* RX-01(2010) at VIII-7, § D.4.

943 *See* RX-01(11/11) at VIII-7, § D.4.

12.5 Program Core – Requirements, Education, Detection & Corrections

12.5.1 Overall CVS, from 2006 to 2014, maintained an incomplete and dysfunctional anti-diversion program related to its distribution of controlled substances.

Although CVS had an advantage over other controlled substances distributors in that the "customers" of its distribution centers were CVS-owned or operated pharmacies, CVS failed to design, implement, operate or maintain an effective anti-diversion program that included the detection and reporting of suspicious orders. CVS and its distribution centers were in the enviable position that access to pharmacy dispensing data was in-house and accessible. However, rather than capitalize on this differentiator by creating an effective program, CVS chose to do as little as possible with regards to controlled substances compliance.

A. 2006 – 2009

During the period from 2006 to 2009, CVS' anti-diversion program hinged on two main processes: "Pickers and Packers" and PDMR reports. However, neither process adequately met the basic parameters of a credible SOM system.

1. Pickers and Packers

The pickers and packers ("P&Ps") were distribution center employees, "who actually pick the drugs, place them in secured totes and see to it that those, then, are transferred for loading on trucks."[944] With the absence of documented criteria for determining when an order was suspicious, the P&Ps were forced to rely on their "gut feeling" or other unvalidated informal rules.[945] For example, Ellen Wilson, who worked in one of the Rx department picking aisles at the Indianapolis DC, described using a rule taught to her by Charlotte Rucker based on hydrocodone bottle sizes:

> She said, [a]s a rule you send out 12 -- no more than 12 of the little ones, six of the big ones and two to three of the bigger -- the large size ones as a rule across the board.[946]

Ms. Wilson was not aware of how many different formulations and strengths that hydrocodone came in and therefore to her, it was permissible to "order 11 little bottles of hydro all different doses and [that] would be

[944] *See* M. Vernazza Deposition at 165:16-20.

[945] *See* E. Wilson Deposition 17:11 - 18:20, 62:3-19; 63:19-24 (January 24, 2019); *see also* G. Milikan Deposition, 147:9-15 and 149:18 -150:3. Training for pickers and packers was only seen referenced in documents dating from August 2013.[945] The "huddle" as the training was called, was intended to remind the pickers and packers about the duty to monitor orders of controlled substances. *See* Email from A. Propatier to J. Meikle, *et al.,* SOM Work Instructions (Aug. 6, 2013), CVS-MDLT1-000003020; Work Instructions for Suspicious Order Monitoring, CVS-MDLT1-000003020 at CVS-MDLT1-000003021 and DC Huddle, CVS-MDLT1-00003028. However, beyond a general reminder, the "huddle" document does not list specific criteria that should be used when judging whether an order is deemed suspicious or not. *Id.*

[946] *See* E. Wilson Deposition at 63:19-24.

okay … "[947] There was also no consideration of what previously was shipped to the pharmacy at all.[948] As a result very few orders were ever flagged by the P&Ps.[949]

The CVS system of using P&Ps as a suspicious order monitoring control is completely ineffective as the P&Ps had no visibility to order histories to evaluate discrepancies in size, frequency or pattern, the fundamental criteria established by the DEA for suspicious orders.[950]

2. PDMR Reports

The PDMR reports (a.k.a. a VIPER reports) were loss prevention reports that "reflected orders in the aggregate and compared those orders to dispensing and looked to see if there were increases in ordering over dispensing, coupled with other indicia that may prompt loss prevention personnel to undertake an investigation."[951] Therefore, they were reports to show how much was shipped to and dispensed from a pharmacy and whether there was a theft of product.[952] There was no evidence presented that formal documented standards governing the use of PDMR reports ever existed.[953]

While CVS represented that PDMR reports were part of the company's efforts to monitor suspicious orders, Mark Vernazza testified:

> [T]his report was not what we deemed a suspicious order monitoring report. It's relevant to orders and order size and, some degree, order pattern. But the point of this was not to produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA.[954]

Furthermore, the reports were deficient as a SOM reports in two important respects. First, the reports did not provide data on unusual order size, frequency or pattern.[955] Second, they were produced at monthly intervals or more and thus provided only a retrospective view that could not be used to block and hold suspicious orders.[956] Therefore, the PDMR reports also were an ineffective anti-diversion control when measured against the DEA's requirements to prevent contemporaneous diversion.

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[947] *Id.* at 67:16-21.

[948] *Id.* at 71:17- 72:13.

[949] *See* Sherri Hinkle Deposition, 83:23 to 86:5 (Jan. 25, 2019) (perhaps one order every six months was flagged).

[950] *See* 21 C.F.R. § 1301.74(b).

[951] *See* M. Vernazza Deposition at 178:20 to 179:4.

[952] *See* Aaron Burtner Deposition at 384:12-22.

[953] *See* F. Devlin Deposition at 420:13-23.

[954] *See* M. Vernazza Deposition at 191:14-21.

[955] *See* A. Burtner Deposition at 383:10 to 384:9.

[956] *See* M. Vernazza Deposition at 192:2-12.

B. 2009 - 2011

The period of 2009 to 2011 saw perhaps the most substantive changes to the CVS SOM and anti-diversion programs. These changes included written standards, automated threshold detection systems, and standardized reporting of "flagged" orders. Despite these modifications, CVS' convoluted implementation of these changes still resulted in an ineffective system to detect, stop and report suspicious orders

1. Controlled Drug – DEA SOP Manual

In early 2007, CVS, with the help of the BuzzeoPDMA group, began work on an SOP manual that was intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring.[957] However, by November, neither the final manual nor the SOM section was complete "[w]e are still in the process of writing the Suspicious Order Monitoring Section of the SOP."[958] Later, when the first version of the SOP manual finally was issued in December 2007, the SOM section still remained incomplete.[959]

By 2009, almost <u>two years</u> after the SOP manual was first distributed, CVS still had not completed the SOM section: "the SOM section is still not incorporated in the SOP, in the event of an audit and the question comes up please direct them to corporate … for the explanation of the program."[960] As Mr. Mortelliti wrote in November 2009, "I am trying to get a rough draft SOM SOP to you prior to the meeting." and he recognized that "[t]his is a big issue with CVS and the DEA."[961] However, despite recognizing this was a big issue, CVS did not incorporate the final missing section until the end of August 2010, and then did so only because of a need to respond to an apparent promise to provide it to the DEA.[962]

Adding further complexity and confusion to CVS' written standards was the fact that the DEA SOP Manual was revised at least four more times between August 2010 and November 2011.[963] So many revisions in such a short time frame is indicative of a compliance program that exhibits poor self-reflection and weak critical thinking. Being in an almost constant state of flux, made it extremely difficult for CVS to ensure the manual's recipients were working with the most current version of the document as well as have all applicable employees trained.

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[957] *See* Letter G. Glatz to F. Devlin, Regulatory Consulting Services, 2 (Mar. 22, 2007) (At that time BuzzeoPDMA was a division of Dendrite, which was later acquired by Cedegim), CVS-MDLT1-000109199 ["BuzzeoPDMA Proposal"]; *see also* Email from A.L. Brown to A. Brumfield, *et al.*, New RX DEA SOP (Nov. 27, 2007) (referring to the *Controlled Drug – DEA Standard Operating Procedures Manual RX-01)*, CVS-MDLT1-000025204; CVS Distribution Centers, *Controlled Drug – DEA Standard Operating Procedures (SOPs) Manual,* Cover page (Nov. 2007) (Showing seven drafts from May 1, 2007 to November 2007), CVS-MDLT1-000025204 at CVS-MDLT1-000025206 ["2007 DEA SOP"].

[958] *See also* Email from A.L. Brown to A. Brumfield, *et al.*, New RX DEA SOP (Nov. 27, 2007), CVS-MDLT1-000025204.

[959] *See* RX-01(2009).

[960] *See* Email from A. Propatier to W. McDaniels, *et al.*, Updated DEA SOP (Apr. 3, 2009) (A. Propatier was formerly A.L. Brown), CVS-MDLT1-000066574.

[961] *See* Email from J. Mortelliti to C. Knight, RE: November 10, 2009 (Nov. 5, 2009), CVS-MDLT1-000087889.

[962] *See* RX-01(2010); *see also* Email from A. Propatier to A. Lamoureux, DEA SOP 08-25-10.doc (Aug. 26, 2010), CVS-MDLT1-000088956; Email from J. Mortelliti to F. Devlin, *et al.*, RE: DEA SOP (Aug. 23, 2010) (referencing Mr. Devlin's earlier email to him stating "we promised this to DEA by Wednesday."), CVS-MDLT1-000089188.

[963] *See* RX-01(11/11) at 1, CVS-MDLT1-000008506 (showing revisions for 8/25/10, 11/29/10,3/11/11, 5/6/11 and 11/8/11).

Also, the fact that CVS revised this manual so frequently (in some cases three or more times per year) suggests that the company could not draft the SOP closely enough to mirror actual operations, or alternatively that CVS kept "tweaking" and testing the process in the hope they could obtain preordained outcomes. Based on how CVS handled the Buzzeo algorithm (discussed later), I believe that the latter is the more plausible explanation.

When it was finally issued in August 2010, the newly revised SOM section covered several topics, including (a) items reviewed, (b) product buildup, (c) the Item Review Report or IRR, (d) review escalation steps, and (e) the suspicious order reports.[964] It also expressly mandated that all CVS distribution centers ("DCs") "must follow these procedures."[965]

In the Items Reviewed section, CVS maintained that:

> CVS has established Control Drug order thresholds which will flag on the IRR (Item Review Report) .... These thresholds are **the primary tool** to prevent stores from purchasing excessive or potentially suspicious Control Drug orders. These thresholds are based on historical trends of sales. Stores may order more than the historical average; however, the DC may not ship amounts that exceed these thresholds if it is believed to be suspicious.[966]

Adopting the prior version of the manual's use of vague language, the section only outlined two possible factors to be considered for determining when an order "is believed to be suspicious," although the DC Pharmacy Supervisor may consider more: (a) known reasons for increased orders such as product shortages or (b) "Corporate promotional activities."[967] Citing just these two examples was disingenuous given the DEA's diversion factors were sent to all registrants in September 2006 and easily could have been incorporated in this 2010 SOP version.[968]

2. Cegedim Compliance Solutions Suspicious Order Monitoring System ("CCS-SOMS")

In March 2007, BuzzeoPDMA proposed and ultimately was engaged for a series of projects with CVS to help with developing an enhanced anti-diversion program focused around suspicious order monitoring.[969] As part of the overall project plan, BuzzeoPDMA planned to "develop a specific significant loss threshold methodology and prepare an SOP specific to controlled substances managed and distributed by CVS" by utilizing "historical data from CVS's distribution facilities in developing the methodology and the schedule specific significant loss thresholds."[970] This work was part of a larger project to assist "CVS in the development of a comprehensive

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[964] *See* RX-01(2010) at VIII-6 to VIII-8, §§ D.1-7 (Control Drug Suspicious Orders).

[965] *Id.* at VIII-6, § D.1.

[966] *Id.* at VIII-7, § D.2.

[967] *Id.* at VIII-7, § D.4(a-b).

[968] *See* DEA 9/27/2006 Letter at 2, CVS-MDLT1-000010552.

[969] *See generally* BuzzeoPDMA Proposal.

[970] *Id.* at 2.

suspicious order monitoring and compliance plan that will allow CVS to operate a system to disclose suspicious orders of controlled substances," with an automated computer program at its core.[971]

With the purchases of BuzzeoPDMA by Cegedim, the automated program became known as the Cegedim Compliance Solutions Suspicious Order Monitoring System or CCS-SOMS. The CCS-SOMS program was "designed to evaluate orders and determine whether they are more likely to fit the DEA's definition of a 'suspicious order' or less likely to fit the DEA's definition of a 'suspicious order.'"[972] If an order is more likely to fit the DEA's definition of a "suspicious order," the CCS-SOMS program "pends" or flags an order that may be suspicious.[973] This determination is made by scoring the order.

The scoring methodology or algorithm was the heart of CCS-SOMS program. The order's score was the result of scoring each order line item against a series of attributes (e.g., order qualities).[974] These attributes included "markers or data calculated from a twelve-month historical database [and] … identifiers - binary variables that must be either yes (assigned a value of 1) or no (assigned a value of 0)."[975] Certain factors had weighted values (e.g., a coefficient) if they were indicative of a suspicious order.[976] The CCS-SOMs program sought "to apply statistical techniques to establish 'norms' and 'deviations' in order that the overall 'suspiciousness' of the order [could] be evaluated," therefore "[a]t its core, the system [used] a heavily modified logistic regression model."[977] In addition, "[t]he model [was] designed so that any order with a score of 0.15 or higher is identified as suspicious, pended, and should be investigated further."[978] Cegedim delivered the first version of the CCS-SOMS system to CVS in December 2008.[979]

3. Item Review Reports ("IRRs")

With the implementation of the CCS-SOM system, the IRR became the vehicle by which "pended" orders, (i.e., orders that scored above 0.15 and thus were "suspicious") were reported out of the system to Loss Prevention. According to the DEA SOP Manual, the IRR report was "an analysis of all Control Drug orders from the stores within the prior 24 hours … [that] identifies orders that are statistically significant or that vary from historical monthly trends based on the previous 6 months as well as the current month."[980]

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[971] *Id.* at 3.

[972] *See* Compliance Solutions Powered by BuzzeoPDMA, *Descriptive Overview Document Cegedim Compliance Solutions Suspicious Order Monitoring Controlled Substances "Retunement"*, 2 (Feb. 2011) (email attachment from H.J. Mortelliti to F. Devlin, FW: The CVS Retunement, (Feb. 2, 2011)), CVS-MDLT1-000114642 ["Retunement Document"].

[973] *Id.*

[974] *Id.*

[975] *Id.*

[976] *Id.*

[977] *Id.* at 3.

[978] *Id.* at 3 (emphasis in original removed).

[979] *Id.* at 1.

[980] *See* RX-01(2010) at VIII-7, § D.4.

The SOP manual also mandated that "The DC Pharmacy Supervisor has primary responsibility for reviewing the report and investigating all orders that may be excessive or unusual."[981] However, despite how use of the IRR was portrayed in the SOP, CVS simply did not follow its own SOP.

As set out in the SOP, the plan to decentralize SOM responsibilities to the individual distribution centers was never implemented.[982] Although the IRR review process was centralized first in the Lumberton DC, it was later transferred to the Knoxville DC and subsequently centralized in Indianapolis.[983] The reasoning behind not decentralizing the SOM process will be discussed later in this report, but its negative impact on the SOM program cannot be overemphasized.

IRR reports were generated daily for each distribution center.[984] According to Mr. Mortelliti, who was reviewing all the daily IRR reports, it was his practice to "freeze" every flagged hydrocodone order that appeared on the IRR by contacting the Loss Prevention Manager and the Pharmacy Manager at the relevant Distribution Center.[985] He stated his process was to also contact the Field Viper Analyst ("FVA") or the Regional Loss Prevention Manager ("RLPM") in order for them to conduct an investigation.[986]

Despite Mr. Mortelliti's contention that CVS froze and investigated every hydrocodone order listed on the IRRs, other testimony and evidence reviewed does not support his claims. At the outset, CVS did not produce, nor could Mr. Mortelliti cite to, any copies of IRRs or other documentation showing that he sent flagged orders to the FVAs for follow up.[987] In fact, Terrence Duggar, the Loss Prevention Manager for the Indianapolis DC,[988] recounting a conversation with a DEA agent during an August 2010 site inspection, stated in a contemporaneous email that:

> I shared with her [the DEA agent] the Suspicious Order Monitoring report (IRR) and she asked how often I received it. I told her daily and weekly, but I have not received the file in a few months as the report was being tweaked. I told her that it was monitored corporately by John Mortelliti. She asked what happens when he calls regarding information on the report, I told her that **I have never received a call regarding information from the report**.[989]

Mr. Duggar also testified that he never monitored any controlled substances.[990]

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[981] *Id.*

[982] *See* RX-01 (2010) at VIII-7 at § 4 ("During the month of September 2010 the report will be transitioned to each pharmacy DC …"); Email from J. Mortelliti to T. Janson, *et al.*, RE: VBDC question (Oct. 12, 2010) ("I will be doing the control drug IRR for the network so there won't be as much confusion trying to decipher the report in its current form."), CVS-MDLT1-000075542.

[983] *See* Discussion *infra*.

[984] *See* J. Mortelliti Deposition 40:7-9.

[985] *See* J. Mortelliti Deposition at 57:16-58:12.

[986] *See* J. Mortelliti Deposition at 54:4-13; 55:2-10; 56:18-24.

[987] *See* J. Mortelliti Deposition at 302:9 to 303:14.

[988] *See* Terrence Duggar Deposition at 20:15-22:8 (Jan. 23, 2019) (Mr. Duggar was the LP Manager from 2005 to November 2010).

[989] *See* Email from T. Duggar to F. Devlin, *et al.*, DEA day 3 (Aug. 26, 2010) (emphasis added), CVS-MDLT1-000010223; *see also* T. Duggar Deposition at 114:10-20.

[990] *See* T. Duggar Deposition at 22:10-15.

With regards to investigating orders, the evidence suggests that CVS in practice rarely investigated flagged orders. This can be seen in the IRR Recap Report. The IRR Recap Report was a periodic report developed by CVS that collected all orders flagged by the daily IRRs over a given time period that were subjected to additional investigation (a.k.a. due diligence).[991]

The report for January 2011 through June 2012 shows that Mr. Mortelliti deemed very few hydrocodone orders as needing additional investigation.[992] Furthermore, it is unclear exactly what type of investigation was performed by the FVAs and RLPMs as Mr. Mortelliti did not maintain any record of their investigations except "when they told [him] it was okay to release the order."[993] He also stated that he thought they used the PDMR (VIPER) reports in their investigation.[994] However, there were no policies and procedures governing how these investigations were conducted to corroborate exactly what was done.[995]

By not following the IRR process as described in the DEA SOP Manual, CVS failed to hold, investigate and report suspicious orders identified by the CCS-SOMs system and recorded on the IRRs. CVS failed to recognize that any orders identified by the CCS-SOMs system and placed on the IRR report were by definition "suspicious" <u>and</u> needed further investigation before being shipped to the pharmacy. In addition, CVS' "token" due diligence did not constitute a credible investigation. Thus, the process as implemented by CVS did not meet the requirements and expectations for an adequate suspicious order monitoring program as defined by the DEA.

4. "Tweaking" the CCS-SOMs System

Faced with the mounting problem that the new system was flagging large numbers of orders, whether real false positives or not, the CVS solution was to "tweak" the CCS-SOMs system to flag orders at a manageable level. In other words, rather than increase headcount to support the SOM program or alternatively taking an in-depth look at its pharmacies' ordering practices to determine what might be the root cause of the problem, CVS simply altered the system to force the desired outcome even though doing so compromised the effectiveness of the CCS-SOMS program.

As recounted by the Cegedim team:

> In July 2009, CVS Staff advised that the current SOM model was "pending" a large number of orders that were **not suspicious on their face** and were **'cleared' by [the] CVS staff**. This can infrequently occur when the model uses data from a fixed, unchanging period of time prior to the model's initial deployment. In light of **CVS' perceived number of "false positives,"** CCS

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991 *See, e.g,* A. Burtner Exh. 440, CVS-MDLT1-000010268 (2013); IRR Recap Report, (Jan. 2011 to Jun. 2012), CVS-MDLT1-000009740.

992 *See* IRR Recap Report, (Jan. 2011 to Jun. 2012), CVS-MDLT1-000009740. The Recap Report shows flagged orders for control drugs (e.g., hydrocodone) as well as pseudoephedrine ("PSE").

993 *See* J. Mortelliti Deposition at 92:8-9.

994 *See id.* at 67:13-68:1.

995 *See id.* at 199:8 to 200:13; *see also* RX01(11/11) at VIII-7 to VIII-8 § D.5.

> statisticians made revision to the CVS model through an adjustment to the algorithm "coefficients."[996]

The coefficient adjustment was provided to CVS in late August 27, 2009.[997] However, by February 2010, CVS determined that the coefficient revisions did not go far enough, and the Cegedim team suggested raising the magnitude of the score from 0.15 to something higher "in small increments."[998] Cegedim also counseled CVS that it was "important to document what you are doing in a way to show the DEA or other authorities that the changes to the pended orders make sense and that the new policy/procedures are based upon too many unwarranted investigations."[999]

Despite Cegedim's cautions, CVS proceeded to aggressively test higher magnitudes, up to 0.21 at first,[1000] but the IRR was "still large even for the most aggressive formula."[1001] CVS finally settled on 0.65 in July 2010, in part because Mr. Mortelitti concluded that he "could find **not one** item worthy of investigation below .65."[1002] However, it appears that Mr. Mortelliti still was not completely satisfied as he suggested that 0.70 "look[ed] a bit more realistic."[1003]

Cegedim, however, expressed its concern writing to CVS stating "[t]hat's quite a departure from the initial threshold, "and suggested that CVS should undertake a "retunement" of the system.[1004] Even after the February 2011 retunement, which reset algorithm for flagging orders back to the 0.15 level, CVS appears quickly to have returned to operating at the 0.65 level.[1005]

5. Lost Order Data

In October 2010 yet another problem with the system was discovered, which ended CVS' attempt to decentralize the IRR review process.[1006] As Mr. Mortelliti described it:

> DEA expects CVS to prevent suspicious orders from being filled out of our DC's. The current IRR does not provide the proper information to meet the DEA's needs. We need control drugs to

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[996] *See* Retunement Document at 1 (emphasis added).

[997] *See* Email from F. Devlin to E. Demetrius, FW: SOM Report (Aug. 27, 2019), CVS-MDLT1-000109623; *see also* Retunement Document..

[998] *See* Email from R. Williamson to F. Devlin, Adjustment to CVS SOM (Feb. 15, 2010), CVS-MDLT1-000110439 at CVS-MDLT1-000110441.

[999] *Id.*

[1000] *See* Email from A. Santhoshraj to J. Mortelliti, RE: Adjustment to the CVS SOM (Mar. 10, 2010), CVS-MDLT1-000110439.

[1001] *See* Email from J. Mortelliti to F. Devlin, FW: Adjustment to the CVS SOM (Mar. 5, 2010), CVS-MDLT1-000111260.

[1002] *See* Email J. Mortelliti to R. Williamson, RE: SOM Update (Jul. 26, 2010) (emphasis added), CVS-MDLT1-000088734.

[1003] *See id.* at CVS-MDLT1-000088735.

[1004] *See* Email from R. Williamson to J. Mortelliti, *et al.*, RE: SOM Update (Jul. 26, 2010), CVS-MDLT1-000088734 at CVS-MDLT1-000088735.

[1005] *See* J. Mortelliti Deposition at 327:12 to 330-24.

[1006] *See* Email from J. Mortelliti to T. Janson, *et al.*, RE: VBDC question (Oct. 12, 2010) ("I will be doing the control drug IRR for the network so there won't be as much confusion trying to decipher the report in its current form."), CVS-MDLT1-000075542.

> be monitored by "active ingredient." Currently the control drugs are monitored by item. The IRR loses all order history when the info on the item changes **causing CVS to be non compliant [sic.] with DEA expectations**.[1007]

The CCS-SOMs system was dependent upon historical data for accuracy, and as Cegedim told CVS "[t]he "retunement" event is a recommended practice to review and possibly re-adjust the SOM model coefficients … **since the model is developed using historical data** that is provided at the start of the design and ordering habits may naturally evolve and change over time."[1008]

By capturing data by item versus active ingredient, the system was vulnerable to changes in the product information such as minor name changes:

> We thought this would be a great idea at the time but what we found was that the system cannot match historical data to an item if the manufacturer changes the name of the item .... Example, Hydro 5 mg can be changed to Hydro mg5. Same item just put the 5 in front of mg. The system cannot match this item because of the change and therefore loses historical data.[1009]

Despite this gap being identified as a high priority with regulatory compliance implications, CVS failed to remedy the problem in a timely manner.[1010] More than <u>seven months</u> (April 2011) after Mr. Mortelliti's "business idea" was submitted, the CVS IT Logistics Team was still inquiring how to prioritize this critical project with the 58 other projects in the Team's work queue[1011] despite a plea from Mr. Mortelliti to the IT Team and to his supervisor, Mr. Devlin, in October 2010 to expedite the fix.[1012]

During this prolonged gap period, Mr. Mortelliti reviewed "the Control Drug IRR [based] on **commonsense** as apposed [sic.] to **IRR Historical Data**." and by trying to manually retrieve historic order data from prior IRRs.[1013] As Mr. Mortelitti noted, "I know, that this is scary …" because the "gap" reduced the effectiveness of the CCS-SOMs even further beyond the high magnitude score as the lack of the historical data rendered the algorithmic score for an order unreliable.[1014]

[1007] *See* John Mortelliti, *Control Drug IRR update*, CVS Pharmacies Business Idea Description (Oct. 6, 2010; MetaData for last revision) (emphasis added), CVS-MDLT1-000034175 ["Business Idea Description"]. In Mr. Mortelliti's deposition the document was identified as being dated October 8, 2010. *See* J. Mortelliti Deposition, 129:11-12.

[1008] *See* Retunement Document at 2 (emphasis added).

[1009] *See* Email from J. Mortelliti to T. Janson, *et al.*, RE: VBDC question (Oct. 12, 2010), CVS-MDLT1-000075542.

[1010] *See* Email from G. Misiaszek to J. Andrade, RE: Logistics Business Support Requests 2011–04-28 (Apr. 29, 2011); CVS-MDLT1-000029864. The attached project plan chart shows a projected completion date of December 31st, 2011).

[1011] *See* Email from G. Misiaszek to J. Andrade, RE: Logistics Business Support Requests 2011–04-28 (Apr. 29, 2011); CVS-MDLT1-000029864.

[1012] *See* Email from J. Mortelliti to G. Mislaszek, *et al.*, Control Drug IRR important info, (Oct. 6, 2010) (requesting help to expedite the fix), CVS-MDLT1-000034168 at CVS-MDLT1-000034169.

[1013] *See id.; see also* J. Mortelliti Deposition at 148:13-149:3 (noting he was alarmed at the amount of effort that was necessary to get the historical data).

[1014] *See* J. Mortelliti Deposition at 160:6-162:4.

C. 2011 to 2014

From 2011 to 2013, CVS aggressively began to make changes to its anti-diversion program and SOM process. However, despite the additional efforts, these changes overall failed to improve the program in a meaningful way. Once more, CVS' convoluted implementation of these improvements simply achieved an ineffective system to detect, report and stop suspicious orders which is neither good compliance nor in conformance with the DEA's expectations.

1. IRR Review Shift to Knoxville

By March 2011, although CVS continued to maintain a centralized IRR review process, responsibility shifted from Mr. Mortelliti at Lumberton DC to Ms. Hinkle's team in the Knoxville DC.[1015] Initially Shannon Miller, Loss Prevention Supervisor was tasked with the daily IRR reviews, but ultimately, Ms. Hinkle gained two Loss Prevention Analysts assigned to the SOM program.[1016] As discussed previously, although Ms Hinkle had these additional resources to support the SOM program, the program remained severely under-resourced.[1017]

2. Use of MicroStrategy

Although it is not completely clear, it appears that the any due diligence follow-up on suspicious orders in the IRR was extremely limited and the only tools available for the due diligence follow-up prior to 2012 were the PDMR (VIPER) reports.[1018] Beginning in February 2012, CVS began incorporating a program called MicroStrategy into the SOM process.[1019]

According to Aaron Burtner, former CVS SOM Manager, MicroStrategy became the primary tool used to investigate flagged orders.[1020] Analysts using MicroStrategy had access to information on patient ID number, doctors, how the drugs were paid for (e.g., cash or insurance), dispensing data, the patient population that was purchasing the drug, information on the pharmacy, and information on the patient.[1021] Thus, the MicroStrategy tool was a significant improvement for order investigation. If MicroStrategy was used, the process was to make note of it and attach it to the IRR report.[1022] The presumption was that if there were no notes attached to the IRR, the analyst did not use MicroStrategy.[1023]

[1015] Email from J. Mortelliti to E. Demetrius, *et al.*, RE: IRR/SOM Retunement BSR_LOG_61148 (Mar. 14, 2011), CVS-MDLT1-000057759; *see also* P. Hinkle Deposition at 26:4 to 27:8; RX-01(11/11) at VIII-7, § D.4.

[1016] *See* P. Hinkle Deposition, 38:4-39:20.

[1017] *See* Discussion *infra*.

[1018] *See* J. Mortelliti Deposition at 67:13-68:1.

[1019] *See* CVS, IRR SOM Review Project Plan Phase 1, ID 17 and 21 (undated) (showing that use of MicroStrategy started on or about 2/28/12), CVS-MDLT1-000114321.

[1020] *See* A. Burtner Deposition at 375:4-9.

[1021] *See* A. Burtner Deposition at 396:23-397:17; *see also* Shauna Helfrich Deposition, 176:3-12 (Jan. 10, 2019)

[1022] *See* A. Burtner Deposition at 308:22-309:2; S. Helfrich Deposition at 25:17-21.

[1023] *See* A. Burtner Deposition at 309:4-9.

CVS, however, limited the use of MicroStrategy to those cases where the analysts conducted additional due diligence or a "deep-dive" on a particular IRR order.[1024] "Deep-dives" were not performed on every order flagged on the IRR, but only on a subset of orders chosen by the daily IRR reviewer.[1025]

According to Aaron Burtner, his review of the IRR report was merely "double-checking the algorithm," rather than a true review based on additional data.[1026] As a result, the selection of orders for additional due diligence was in essence random. Since the use of MicroStrategy was limited, CVS simply continued its practice of poor due diligence.

3. AGI's Store Metrics

By October 2012, CVS was not satisfied with the outcome of Cegedim's efforts to address the problems with the CCS-SOM system and so brought AGI on board to "develop an algorithm to fix issues with [the] existing algorithm used for the SOM system."[1027] However, as CVS informed AGI, the algorithm was not the only issue needing attention. During the initial discussion and planning phase, CVS told AGI that:

1. "For consistency, the SOM process is reviewed at a central location for all 11 RX DC's."
2. CVS was using eight (8) algorithms.
3. Out-of-stock products could be ordered from an outside vendor, but those orders "are not pushed through the SOM process."
4. The IRR process identified "irregular orders," which were subject to further (unspecified) review, and the DC was contacted not to ship the order until cleared.[1028]

Thus, even as late as October 2012, CVS's anti-diversion efforts continued to be plagued by severe deficiencies undermining any efforts to achieve a good controlled substances compliance program.

Delivered at the end of 2012, AGI Store Metrics was the successor program to the MicroStrategy tool.[1029] While the Store Metrics program provided the same information as MicroStrategy, its primary advantage was that it put that information into one combined dashboard for review[1030] and "greatly reduced the amount of time required to review these [flagged] orders as the [Store Metrics] report generates in a few seconds rather than a few minutes required for MicroStrategy."[1031] CVS replicated the MicroStrategy process, and analysts using

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[1024] *See* A. Burtner Deposition at 267:5 to 268:16, 308:16-20.

[1025] *See* A. Burtner Deposition at 268:17 to 269:1.

[1026] *See* A. Burtner Deposition at 459:19 to 460:15.

[1027] *See* Email from P. Hinkle to F. Devlin, Conference Call Notes - 10 5 12.docx, (Oct. 5, 2012) (referencing notes taken by Aaron Burtner, SOM Manager), CVS-MDLT1-000033579.

[1028] *See* AGI/CVS Discussion, Pharmacy/DC Ordering Process conference call recap, 1-2 (October 5, 2012), CVS-MDLT1-000033580.

[1029] *See* Email from A. Burtner to D. Vanelli and P. Hinkle, Attorney Client Privilege – Store Metrics Report, (Dec. 20, 2012), CVS-MDLT1-000109775; *see also* A. Burtner Deposition at 394:1-5 (Store Metrics becoming the go-to report).

[1030] *See* A. Burtner Deposition at 311:14-18.

[1031] *See* Email from A. Burtner to D. Vanelli and P. Hinkle, Attorney Client Privilege – Store Metrics Report, (Dec. 20, 2012), CVS-MDLT1-000109775.

Store Metrics would attach the reports to the IRR, and if an IRR had no Store Metrics report attached, it was an indication that the analyst had not used Store Metrics.[1032] However, the new program was not without its own problems.

As Mr. Burtner communicated to Mr. Vanelli and Ms. Hinkle in late 2012, "the dispensing data populated on this report is from June 2012-Aug 2012, so the data is already 3 months old and quickly approaching 4 months old."[1033] Consequently, Mr. Burtner recommended that CVS needed "to leverage AGI to give us the ability to update the database used for this report [so we] could then decide how often we want to update the database and keep this information more current; we could potentially have the database updated systematically every Saturday night"[1034] It is unclear if the problem was ever addressed.[1035]

In 2013, CVS began work on creating a SOM application within its Archer platform.[1036] Archer is an integrated software platform for managing risks and controls on an enterprise-wide basis.[1037] The purpose of the Archer application was "to capture all the due diligence conducted on orders of interest" including data generated using the Store Metrics system.[1038] However, the AGI "stale" data problem persisted into July 2013 as Kelly Baker, who reported to Mr. Burtner,[1039] highlighted when he wrote in an email that "[t]he data snapshot is a 3 month window that is a year old [and any] analysis I make from that data is, for the most part, **irrelevant and pointless.**"[1040] Given that the dispensing data used by the Store Metrics application comes from CVS' own pharmacies, it is inconceivable why the current, refreshed data could not be included in the Store Metrics platform as Mr. Burtner suggested. However, not doing so rendered the application ineffective as a due diligence tool.

4. Negating the Benefits of MicroStrategy and Store Metrics

The MicroStrategy and Store Metrics reports provided useful data to investigate suspicious orders as the DEA expects. However, CVS implemented processes that effectively undercut the usefulness of the tools. This meant that the CVS SOM process, and by extension the anti-diversion program did not prevent CVS pharmacies from receiving orders being diverted and did not meet the required standards for a good compliance program.

[1032] *See* A. Burtner Deposition at 311:24-312:14 and 315:7--316:5.

[1033] *See* Email from A. Burtner to D. Vanelli and P. Hinkle, Attorney Client Privilege – Store Metrics Report, (Dec. 20, 2012), CVS-MDLT1-000109775.

[1034] *Id.*

[1035] *See* A. Burtner Deposition at 394:15-18.

[1036] *See* Craig Schiavo, Year-End Review – 2013 (Finalized), 3, (Mar. 4, 2014), CVS-MDLT1-000120580.

[1037] *See* RSA, RSA ARCHER PLATFORM, https://www.rsa.com/en-us/products/integrated-risk-management/archer-platform (last accessed Mar. 10, 2019).

[1038] *See* Craig Schiavo, Year-End Review – 2013 (Finalized), 3 (Mar. 4, 2014), CVS-MDLT1-000120580.

[1039] *See* Kelly James Baker Deposition, 23:11-13, (Jan. 24, 2019).

[1040] *See* Email from K. Baker to C. Schiavo, RE: Archer SOM, (Jul 11, 2013), CVS-MDLT1-000078116 at CVS-MDLT1-000078117.

a. Continuing the Previous IRR Process

CVS' continued use of its past process for handling the IRR reports essentially negated the benefits achieved by these tools. CVS persisted in allowing the daily IRR reviewer to maintain overall control of the investigative process by selecting those orders needing a "deep-dive." However, as discussed previously, the daily IRR reviewer had vested interest in keeping flagged orders to a minimum.

The effect of this continued approach to the daily IRR review is readily apparent in the LP Analyst Studies created by Mr. Burtner. The LP Analyst Time Studies identified IRR flagged orders that were sent on for further investigation beyond the IRR. Below is a chart showing a representative twelve days in 2012, which demonstrates how few orders were sent for investigation across Mr. Burtner's five distribution centers:[1041]

SUMMARY OF AARON BURTNER LP ANALYST TIME STUDIES (JUNE-JULY 2012)[1042]

Exhibit	IRR Date	Time to Review IRR	# of Orders Investigated
Burtner Ex. 411	6/14/12	55	0
Burtner Ex. 412	6/15/12	30	0
Burtner Ex. 412	6/17/12	35	1
Burtner Ex. 413	6/14/12	60	3
Burtner Ex. 414	7/3/12	15	0
Burtner Ex. 414	7/4/12	20	0
Burtner Ex. 415	7/6/12	35	0
Burtner Ex. 415	7/8/12	40	0
Burtner Ex. 415	7/11/12	35	1
Burtner Ex. 416	7/17/12	50	0
Burtner Ex. 417	8/21/12	30	0
Burtner Ex. 418	9/6/12	15	2

Gary Millikan, who also helped review IRRs beginning in August 2013,[1043] testified that of the flagged orders that appeared on the IRR, he did due diligence on probably less than 5% of the orders.[1044] For the remainder (i.e., 95%), he went no further than reviewing the IRR, which provided no additional insights into whether a suspicious order flagged by the algorithms actually involved diversion and consequently should never be shipped to the customer.

[1041] *See* A. Burtner Deposition at 329:18-330:3.

[1042] See A. Burtner Deposition at 340-366 and Burtner Exh. 500.

[1043] See Gary Millikan Deposition, 41:5-15, (January 11, 2019).

[1044] See G. Millikan Deposition at 213:25-214:20; 223:25-224:4; 232:8-14.

b. Ordering from Outside Vendors

Regardless of what set of algorithms and tools CVS used to run its suspicious order monitoring program, the system output never provided the controlled substances compliance team with a complete picture of a CVS store's ordering pattern for hydrocodone. In addition to placing orders with a CVS-controlled distribution center, CVS stores also had the ability to order hydrocodone products directly from an outside vendor (e.g., McKesson or Cardinal).[1045]

However, even though CVS maintained pharmacy-specific data on every CVS store, the SOM system had no access to that data and no visibility to the outside vendor orders.[1046] The IRR did not consider outside vendor orders when determining if an order was suspicious. This "loophole" created issues for CVS including the fact that "[stores} may order a little from both the OV [Outside Vendor} and the DC to stay under the radar" and in one case CVS had "a store, which had a 68,000 hydrocodone pill loss and was placing phone orders to [an] OV."[1047]

This "loophole" made it impossible for CVS to fulfill its "Know Your Customer" obligations of which it admits being aware of back in 2008.[1048] Furthermore, this "loophole," which existed well before the 2012 discussions referenced here,[1049] was still was not closed as of July 2013;[1050] once more illustrating CVS' reluctance to undertake the necessary system improvements to achieve an effective suspicious order monitoring program.

12.6 Accountability - Consistent Enforcement

12.6.1 CVS did not hold employees accountable for failing to maintain and operate an effective anti-diversion program.

There was no evidence presented to demonstrate that CVS held employees accountable for its failed anti-diversion program. In fact, crucial employees, with responsibility for shaping, maintaining and operating CVS' anti-diversion program (e.g., Frank Devlin, John Mortelliti, and Ron Link) continued in positions of substantial authority with CVS even after the failure of its controlled substances compliance program. By failing to hold individuals in substantial authority accountable for the controlled substances program's established lack of effectiveness, CVS's professed commitment to controlled substances compliance is hollow.

[1045] *See* M. Vernazza Deposition at 46:20 to 47:14.

[1046] *See* J. Mortelliti Deposition at 210:17-212:20; *see also* Email from P. Hinkle to F. Devlin, Conference Call Notes - 10 5 12.docx, (Oct. 5, 2012) ("All orders generated for Outside Vendors are not pushed through the SOM process."), CVS-MDLT1-000033580.

[1047] *See* Email from C. Schiavo to T. Bourque, Monday Morning Meeting w/ Tom P, (Jan. 18, 2013), CVS-MDLT1-000103329.

[1048] See M. Vernazza Deposition at 148:5-14; *see also* Discussion *infra* (concerning CVS Stores #3322 and #4800).

[1049] *See* M. Vernazza Deposition at 46:20 to 47:14; D. Vanelli Deposition at 75:16-18. While no start date is specified, the testimony of both Messrs. Vernazza and Vanelli seem to indicate that CVS stores always had this ability.

[1050] *See* D. Vanelli, *Logistics Planning Update*, 3 (Jul. 8, 2013) ("SOM process will include store controlled substances orders placed with … outside vendors."), CVS-MDLT1-000100362.

13 Walgreens Boots Alliance, Inc.

13.1 Background

Walgreens Boots Alliance, Inc. ("Walgreens" or "WBA") began in 1901 as single pharmacy on Chicago's southside owned and operated by Charles R. Walgreen, Sr.[1051] Since 1901, WBA has grown into a global company with sales of $131.5 billion for FY 2018.[1052] Formed in 2014 from the merger of Walgreens and Alliance Boots, WBA combined the largest U.S. drugstore chain with Europe's largest pharmaceutical wholesaler.[1053] As of the end of FY 2018, Walgreens employed more than 415,000 people, and the combined company operated over 18,500 stores in 11 countries under the banners of Walgreens, Duane Reade, Boots and Alliance Healthcare.[1054] In addition, WBA maintains a pharmaceutical wholesale and distribution network that includes over 390 distribution centers.[1055] Within the U.S., Walgreens' employs more than 240,000 people and currently maintains more than 9,500 stores.[1056]

Walgreens, in March 2013, entered into a series of agreements with AmerisourceBergen that has resulted in WBA owning, by the end of FY 2017, 26% of AmerisourceBergen's common stock in exchange for a ten-year pharmaceutical distribution agreement.[1057] In 2015, WBA attempted to acquire Rite Aid, but by 2017 in the face of Federal Trade Commission ("FTC") pressure, WBA chose instead to acquire 2,186 (almost 50%) of Rite Aid stores.[1058]

From a corporate compliance perspective, Walgreens has had a Chief Compliance Officer since 1999 when Chester G. Young was appointed to the role for Walgreen Co.[1059] Since that time Walgreens has had three

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[1051] WALGREENS BOOTS ALLIANCE, INC., *History*, https://www.walgreensbootsalliance.com/about/history/ (last visited Feb. 20, 2019). It should be noted that the defendants in this matter are Walgreens Co. and Walgreens Eastern Co, both of which are subsidiaries of WBA.

[1052] *See* Walgreens Boots Alliance, Inc., *Annual Report 2018*, 1 (Oct. 24, 2018) ["WBA 2018 Annual Report"].

[1053] *See* Ellen Jean Hirst, *Walgreen-Alliance Boots deal is complete*, Chicago Tribune (Dec. 31, 2014, 9:30 AM), https://www.chicagotribune.com/business/ct-walgreen-completes-merger-0101-biz-20141231-story html.

[1054] *Id.*

[1055] *Id.*

[1056] *See* WALGREENS, *Facts & FAQs*, https://news.walgreens.com/fact-sheets/frequently-asked-questions.htm (last visited Feb. 7, 2019).

[1057] *See* Walgreens Boots Alliance, Inc., *Annual Report 2017*, 1-2 (Oct. 24, 2017).

[1058] *See* David Goldman, *A drug store deal gone bad: Walgreens merger with Rite Aid falls apart*, CNN BUSINESS (Jun. 29, 2017, 10:19 AM ET), https://money.cnn.com/2017/06/29/news/companies/walgreens-rite-aid/index html.

[1059] *See* Jim Frederick, *Walgreens veteran Young to retire: Merten stepping into compliance role*, Drug Store News (Nov. 30, 2009) at https://www.drugstorenews.com/news/walgreens-veteran-young-retire-merten-stepping-compliance-role/

changes in its Chief Compliance Officer with Laura Merton (2010 to 2013),[1060] Diane Nobles (2013-2016),[1061] and Matthew D'Ambrosio (2017 to present)[1062] all serving in the role.

In 2008, Walgreens entered into a five-year Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services, Office of Inspector General ("OIG") to settle a series of cases involving healthcare fraud and false claims involving Medicaid reimbursements and the company's Therapeutic Interchange Program.[1063] Once more in January 2019, Walgreens entered into another five-year Corporate Integrity Agreement and agreed to pay almost $270 million to settle false claim allegations of improperly billing healthcare programs.[1064]

From a controlled substances perspective, the relevant time period for this review is 1998 to 2014 during which Walgreens maintained its own internal distribution network that supplied controlled substances to its retail stores.[1065] That internal distribution network, however, did not meet all of Walgreens' retail needs and Walgreens' stores also fulfilled some of their controlled substances needs from the Group 1 distributors.

By 2012, Walgreens had thirteen (13) distribution centers ("DCs") capable of distributing controlled substances, and of those, only three (3) handled Schedule II controlled substances (Jupiter, Florida; Perrysburg, Ohio; and Woodland, California).[1066] On September 13, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order ("OTC and ISO") to Walgreens asserting that the Jupiter distribution center constituted "an imminent danger to the public health and safety."[1067]

In February 2013, the DEA issued similar Subpoenas and a Warrant of Inspection on the Perrysburg Distribution Center in Ohio for issues similar to those which the DEA found with the Jupiter DC in Florida and which ultimate led to the Jupiter DC's license being suspended and its vault being padlocked.[1068] Within weeks of receiving the six subpoenas and the warrant, Walgreens decided to "discontinue distribution of controlled

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[1060] *Id.*; *see also* Laura Merton LinkedIn Profile, https://www.linkedin.com/in/lauramerten/ (last accessed Feb. 12, 2019).

[1061] *See* Diane Nobles LinkedIn Profile, https://www.linkedin.com/in/dbnobles/ (last accessed Feb. 12, 2019) (Prior to joining Walgreens, Ms. Nobles served as Senior Vice President, Compliance & Integrity at CVS Caremark).

[1062] *See* Matthew D'Ambrosio LinkedIn Profile, https://www.linkedin.com/in/mattdambrosio/ (last accessed Feb. 12, 2019).

[1063] *See* FDAnews Drug Daily Bulleting, Walgreens Settles Investigations Related to Medicaid Reimbursements, FDANEWS (Jun. 6, 2008), https://www fdanews.com/articles/107388-walgreens-settles-investigations-related-to-medicaid-reimbursements; *see also* Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Walgreen Co. (Jun. 2, 2008) ["Walgreens 2008 CIA"].

[1064] *See* Beth Jones Sanborn, *Walgreens settles False Claims suits for $270 million*, HEALTHCARE FINANCE (Jan. 24, 2019), https://www.healthcarefinancenews.com/news/walgreens-settles-false-claims-suits-270-million.

[1065] However, there is some evidence suggesting that Walgreens had a SOM process before 1998. *See, e.g.,* Email from D. Coughlin to Marcella Ranick, *et al.*, Re: Suspicious Controlled Drug Orders, (August 3, 2010), WAGMDL00660331.

[1066] *See* Walgreens Boots Alliance, *Walgreen Co. Controlled Substance Anti-Diversion and Compliance Program*, 12 (Jul. 17, 2012), WAGMDL00659802 ["WBA CS Program 2012"].

[1067] *See* Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), WAGMDL00387653 at WAGMDL00387654 ["Jupiter Show Cause Order"].

[1068] *See* In the Administrative Matter of Walgreens Corporation, (W.D. Ohio 2013), WAGMDL00493697; U.S. Drug Enforcement Administration Subpoenas to Walgreens Corporation, 17-13-7042 (2013), WAGMDL00493694.

substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.[1069]

The Jupiter OTC and ISO and the Perrysburg investigation resulted in Walgreens and the DEA entering into a settlement agreement in 2013 to resolve what the DEA noted as "systemic" issues.[1070] As part of that settlement, Walgreens agreed to undertake various prospective compliance measures that impacted all of Walgreens's controlled substances distribution centers.[1071] Facing mounting pressures and increased enforcement surrounding the distribution of opioids together with signing a long-term distribution arrangement with ABC, Walgreens ceased self-distributing Schedule II controlled substances in 2013. With the reclassification of hydrocodone combination products ("HCPs") from Schedule III to Schedule II,[1072] Walgreens, by October 2014, ended internal distribution of all controlled substances shifting distribution of controlled substances to its outside partner, AmerisourceBergen.[1073]

13.2 Executive Summary

The overall theme to the Walgreens' controlled substances compliance program is "too little, too late." Even though Walgreens operated licensed distribution centers to supply its stores with controlled substances from 1998, Walgreens made little attempt to design and operate an effective anti-diversion program that identified and reported suspicious orders to the DEA.

That began to change somewhat in 2008 in response to the DEA action taken against Walgreens's then-primary vendor, Cardinal Health.[1074] At that point, Walgreens embarked on an effort to develop an improved and automated anti-diversion program. However, it took several more years (until 2012), and the threatened loss of at least one of its three Schedule II controlled substances distribution centers for Walgreens to begin to take meaningful steps towards implementing a credible controlled substances program. Meanwhile, by March 2013 and the signing of the ABC distribution agreements, Walgreens had decided to cease distributing controlled substances, preferring instead to outsource it to a strategic partner in which Walgreens held a substantial equity stake.

Some of the key contributing factors to this "too little, too late" approach and the failure of Walgreens to take its corporate anti-diversion obligations seriously include:

[1069] *See* Letter from Alice S. Fischer, *et al.*, to C. Lee Reeves, II, *et al.*, Walgreens Perrysburg, Ohio Distribution Center, (Feb. 20, 2013), WAGMDL00674280.

[1070] *See* Settlement and Memorandum of Agreement between the U.S. Department of Justice, U.S. Drug Enforcement Administration and Walgreen Co. (Jun. 10, 2013), WAGMDL00490963 [Walgreens SMOA].

[1071] *See* Walgreens SMOA at Addendum: Prospective Compliance (Jun. 10, 2013), WAGMDL00490963 at WAGMDL00490976.

[1072] *See* 79 Fed. Reg. 49661 (Aug. 22, 2014).

[1073] *See* E. Bratton Deposition at 141:3-4 (Edward Bratton, a Manager in Walgreens Pharmaceutical Integrity, was Walgreens' 30(b)(6) witness) ["E. Bratton Deposition"]

[1074] See, Email from M. Bleser to J. Berkowitz, *et al.*, RE: Update (Apr. 6, 2012) ("In March 2008, a team consisting of Rx Purchasing, Logistics, Legal, Loss Prevention and Store Order System IT began creating the Suspicious Order Monitoring Process in response to the Cardinal incident in which 3 of their DCs were shut down by the DEA for suspicious drug ordering violations"), WAGMDL00709395.

- **Singular Retail Focus:** As one of the top three retail pharmacy chains in the U.S., Walgreens' efforts to manage controlled substances compliance focused primarily on ensuring its anti-diversion program did not impinge on the retail stores' ability to obtain the volume of opioid products that that the stores requested. Consequently, Walgreens failed to implement effective anti-diversion measures that would regulate or limit a store's ability to obtain uncontrolled amounts of opioids. This singular retail focus was couched and cloaked under the mantle of "you [have] got to take care of [the] patients,"[1075] which merely allowed Walgreens to protect its retail market and justify its noncompliance with its anti-diversion obligations.

- **Lack of Time, Attention & Resources:** Internally, distribution center compliance with SOM and anti-diversion requirements did not receive the time, attention, and resources it deserved. This occurred despite ample available information demonstrating that Walgreens knew or should have known what its obligations as a controlled substances distributor were.[1076] It also occurred because the team charged with controlled substances compliance (e.g., Pharmaceutical Integrity, Rx Purchasing, Logistics, Legal, Loss Prevention, & Store Order System IT) did not appreciate that opioids were not "widgets" and thus required special focus at the distribution level.

- **Over-Reliance on Technology:** Within Walgreens, a widespread belief emerged that the Bancroft algorithm and the CSOM system were the solutions to the Walgreens anti-diversion and suspicious order monitoring obligations. Therefore, Walgreens placed undue faith in and reliance on its technologic prowess for inventory management. Consequently, Walgreens did not appreciate that while well-designed technologic solutions were good at identifying outliers, these solutions were not good at resolving those discrepancies. Thus, Walgreens neglected the human element in the compliance equation as demonstrated in the non-IT portions of its program. This faith and overreliance on a technology-driven approach to suspicious order identification and controlled substances compliance were precisely what Joseph Rannazzisi cautioned against in his December 2007 letter to all DEA registrants.[1077]

When taken together from 1998 to 2014, Walgreens' controlled substances compliance program was inadequate, and, in my opinion, did not rise to the foundational level on the compliance maturity and program effectiveness model. This failure is particularly troubling given the fact that Walgreens was subject to a Corporate Integrity Agreement during this period, in addition to its DEA settlement, that should have caused the company to take its compliance obligations more seriously than it did.

13.3 Impact

Walgreens activities in Ohio were the predictable result of the company's failure to maintain a credible anti-diversion program. For example, a suspicious order report ("SOR") showing store orders from approximately

[1075] *See, e.g.,* N. Polster Deposition, 144:2 (Jan. 23, 2019); *see also* Email from K. Crawford to S. Hasen, *et al.*, FW: OXYCODONE no longer being ordered via PDQ (Oct. 1, 2012) ("We have to do what's right for patients also."), WAGMDL00705321. Mr. Crawford was President of Walgreens Health and Wellness division.

[1076] *See* Jupiter Show Cause Order at ¶¶ 7-8.

[1077] *See* Letter from J. Rannazzisi to All Registrants (Dec. 27, 2007).

February to August 2010 nationwide contains 1,712 pages.[1078] Below are just a few examples illustrating how Walgreens'' anti-diversion program failures translated into various Walgreens stores obtaining high levels of opioids with little or no investigation or interrogation.

Walgreens Store 3226

In the case of Store 3226 located at 6410 Broadway Avenue in Cleveland, the SOR report shows that this store in March, April, and June 2010 obtained 2,200, 2,100 and 2,800, dosage units respectively of oxycodone per month when its limit was 1,800 dosage units (600 base dosage units x factor of 3).[1079] Thus, the store was allowed by Walgreens to exceed its limit even with a buffer of 1,200 dosage units per month factored in.

Store 3226, in August 2013, also reported that even though its allocation was increased in June, it needed to be increased again.[1080] Walgreens' Pharmaceutical Integrity increased the allocation again without taking into account that Store 3226 was repeatedly out of compliance in 2010 and even went so far as to suggest that the store in the interim before the new allocation becomes effective could order additional bottles via the PDQ process.[1081]

Walgreens Store 3314

From 2006-2014, Store 3314, located at 5400 Pearl Road, Parma, Ohio, obtained on average 276,900 dosage units of oxycodone and 259,420 dosage units of hydrocodone per year from both Walgreens distribution centers, as well as Cardinal Health, Anda and AmerisourceBergen.[1082] While the annual averages are high, those numbers do not show the complete picture. Store 3314 purchases of oxycodone from 2006 to 2010 reveal a precipitous year-on-year increase as outlined below.[1083]

Walgreen Store 3314 Oxycodone Purchase by Year

YEAR	DOSAGE UNITS
2006	168,200
2007	199,000
2008	242,100
2009	299,000
2010	361,100

[1078] *See* Suspicious Drug Control Orders Report (Aug. 2, 2010); WAGMDL00183798 at WAGMDL00183799 ["SOR"]; E. Stahmann Deposition at 290:24 to 291.15 (Oct. 16, 2018).

[1079] *See* SOR at WAGMDL00205380.

[1080] *See* Email from P. Daugherty to J. Whited, RE: Percocet (Aug 9, 2013) (referencing email from Pharmacy Manager 03226 to J. Whited on Aug. 9, 2013), WAGMDL00698150.

[1081] *Id.*

[1082] *See* Opioid Shipments to BW4673554 by Distributor 2006-2014, Exhibit 13 to Deposition of Eric Stahmann.

[1083] *Id.*

Thus, from 2006 to 2010, the store's annual number of dosage units increased by an astounding 214.68%. However, Walgreens continued shipping oxycodone to the store from its own distribution centers and allowed it to continue purchasing from the other outside distributors without interruption and without the proper due diligence documentation demonstrating a legitimate basis for this increase.

Walgreens Store 12444

Store 12444, located at 3415 Clark, Cleveland, Ohio, submitted a CSO Override form to increase its allotment of oxycodone with acetaminophen 5mg/325mg to 2,000 dosage units per week (8,000 per month).[1084] The rationale provided for the increase was that the store averages 600 opioid prescriptions per day because it serves an emergency room, hospital, pain management clinic, and hospice care.[1085] Despite the "red flag" indications of potential diversion, Mayur Tailor from Pharmaceutical Integrity approved the increase less than 24 hours later stating that although the store had reached its product allotment, the increase was approved "after reviewing the item movement."[1086] Thus, the limit was increased simply to accommodate the sales line, and not because an investigation revealed that diversion was unlikely to occur.

13.4 Company Commitment – Compliance Culture, Organization & Resources

13.4.1 Walgreens was so focused on the retail stores that it resisted and ultimately failed to adopt anti-diversion measures that would regulate or limit a retail store's ability to obtain uncontrolled amounts of opioid products.

Walgreens singular focus on its retail stores was cloaked by the mantra of "you have to take care of the patient." As a result of this retail focus culture, it was not until the company was forced to confront the magnitude of its noncompliant situation with the Jupiter Order to Show Cause, that Walgreens began making substantive changes to its controlled substances compliance program:

> [T]he Company has enhanced its suspicious order monitoring program for controlled substances in an effort to convince DEA that the proposed penalty is excessive and that our new processes will ensure that similar incidents do not recur.[1087]

For example, when describing Walgreens' pre-2013 suspicious order system, Natasha Polster, former head of the Pharmaceutical Integrity department stated, "the system was **designed** and built way back in the day to ensure that the store was able to get the product in that they need **to take care of their patients**."[1088] Even after

[1084] *See* Email from J. Whited to RxIntegrity, Controlled Substance Order Quantity Override Form, (Jun. 18, 2013 at 3:18 PM), WAGMDL00698296 at WAGMDL00698297.

[1085] *Id.*

[1086] *See* M. Tailor to J. Whited, RE: Controlled Substance Order Quantity Override Form, (Jun. 19, 2013 at 9:25 AM), WAGMDL00698296.

[1087] *See* Email from T. Polster to D. Doyle, FW: Proposed org chart, at 2 (Dec. 16, 2012) (Doyle was Vice President of Finance), WAGMDL00659270.

[1088] *See* N. Polster Deposition at 161:11-14 (emphasis added).

the Bancroft algorithm was in use, Ms. Polster stated that the system "was designed so we could ensure that the number of tablets … that goes into any store makes sense for the peer group and business of that store."[1089]

The Pharmaceutical Integrity Department, which as of 2012 was charged with overseeing Walgreens' SOM system, viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism:

> Q: Now, Walgreens' system, similar to my alarm, is there to detect a potential red flag. Would you agree with that?
>
> A: It was put in place to **ensure that the stores had the proper quantities**. **Not necessarily to … detect a red flag**. The whole idea was to make sure that the stores were getting the quantities that they needed based on their peer group.[1090]

Consequently, from an inventory management perspective, "the whole point behind it [the system] was to have simplicity,"[1091] instead of focusing on Walgreens' anti-diversion obligations. Denman Murray, Director of Rx Supply Chain Retail, echoed this when he said in his deposition, "traditionally, we've always treated a controlled substance like any other, **[a] widget's a widget to the system**."[1092]

13.4.2 From 2008 to 2013, Walgreens has failed to integrate its controlled substance compliance efforts with the corporate compliance program in any meaningful way.

With its 2008 Corporate Integrity Agreement, Walgreens agreed to continue its voluntary compliance program, including maintaining both a Chief Compliance Officer and a Compliance Committee for a period of five-years (through at least June 2013).[1093] Walgreens also agreed to maintain its Pharmacy Code of Conduct.[1094]

A. Codes of Conduct

Walgreens currently maintains two separate and distinct Codes of Conduct. The first is the WBA Code of Conduct and Business Ethics ("Business Ethics Code"), and the second is the Walgreens' Pharmacy and Healthcare Professionals Commitment to Compliance ("Pharmacy Code").[1095] The Pharmacy Code, formerly

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[1089] *See id.* at 175:4-7. For a description of the Bancroft algorithm, see section 8.3.2 below.

[1090] *See id*. at 223:13-23 (emphasis added).

[1091] *Id.* at 175:10-11.

[1092] *See* D. Murray Deposition, 31:20-22 (Jan. 15, 2019) (emphasis added).

[1093] *See* Walgreens 2008 CIA at §§ I and III.A.

[1094] *See id.* at § III.B (The full title of the document was "Walgreens Pharmacy and Health Care Code of Conduct Policy").

[1095] *See* Walgreens Boots Alliance, *Code of Conduct & Business Ethics* (Nov. 2017), https://investor.walgreensbootsalliance.com/static-files/b618a6e0-100d-4f35-a980-57c2c36089b1 ["Business Ethics Code"]; Walgreens, *Pharmacy and Healthcare Professionals Commitment to Compliance*, Policy WAG-POL-PHA-001, Version 1.0 (Feb. 16, 2017), WAGMDL00254921["Pharmacy Code 2017"].

known as the "Walgreens Pharmacy and Health Care Code of Conduct and General Training," traces its origins back to July 2008 and is the Code referenced in the 2008 Corporate Integrity Agreement.[1096]

Despite having two codes of conduct, Walgreens has not expressly linked them together. For example, while the Business Ethics Code is the responsibility of Walgreens' Chief Compliance Officer, the Pharmacy Code is "owned" by the Senior Vice President of Pharmacy and Retail Operations. The Codes also have two different foci.

The Business Ethics Code "defines how you should conduct yourself as an employee or representative of WBA" and it addresses the responsibilities of WBA officers and employees "to each other, and to customers, suppliers, consumers, and governments."[1097] WBA positions the Business Ethics Code as "a resource to be used to help guide your actions and provides details on **where to go for more information on a particular subject**, to ask questions, or to report a problem."[1098]

Under the Business Ethics Code, compliance with controlled substances requirements is not specifically highlighted. The closest the Business Ethics Codes comes to addressing that "particular subject" is located in the "A Foundation of Trust for Our Communities—We comply with healthcare laws" section that was expanded in October 2015.[1099] The Business Ethics Code states:

> WBA is committed to full healthcare law compliance internationally. All businesses must comply with all laws relating to the commercialization and distribution of healthcare products and the conduct of business in the healthcare industry.[1100]

The section contains no reference to the Pharmacy Code or to the Senior Vice President of Pharmacy and Retail Operations. Instead if employees have questions, they are directed to contact their "manager, legal department or the Global Chief Compliance and Ethics Officer."[1101]

The Pharmacy Code, on the other hand, "covers the expected conduct and ethical principles for all Walgreens Family of Companies team members who work in the pharmacy, Healthcare Clinic or handle any prescription drugs."[1102] It specifically includes distribution center personnel and mandates compliance with requirements

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[1096] *See, generally* Pharmacy Code 2017; *see also* Walgreens 2008 CIA at § III.B. The Pharmacy Code has been revised multiple times since 2008 (e.g., 2009, 2010, 2011, 2012, and 2013). A more detailed discussion of those pre-2017 versions can be found in later in the report). Discussion and reference to the Pharmacy Code in this section is limited to the 2017 version (Policy WAG-POL-PHA-001, Version 1.0).

[1097] *See* Business Ethics Code at 6.

[1098] *Id.* (emphasis added).

[1099] *See* Business Ethics Code at 31; *see also* Walgreens Boots Alliance, Notice Regarding Update Walgreens Boots Alliance, Inc. Code of Conduct and Business Ethics (Oct. 20, 2015), https://investor.walgreensbootsalliance.com/static-files/90962a02-97b7-48b7-b849-4e26c5ed0b96.

[1100] *See* Business Ethics Code at 31. Prior to the October 2015 expansion, the 2014 Walgreens Code of Business Conduct had a much narrower focus addressing only "clinical and regulatory standards" and laws "designed to prevent, detect and punish fraud, waste and abuse." *See* Walgreens, Walgreens Code of Business Conduct, 19 (Oct. 2014) at https://www readkong.com/page/walgreens-code-of-business-conduct-8174589.

[1101] *Id.*

[1102] *See* Pharmacy Code 2017 at 1.

"Preventing and Mitigating Diversion of Controlled Substances."[1103] The Pharmacy Code, furthermore, does not state expressly that it is a subset of or in addition to the Business Conduct Code. Consequently, Pharmacy and Health Care Professionals could view the Pharmacy Code as the only Code of Conduct they need to follow.

The maintenance of two separated and unlinked Codes of Conduct increases complexity and the likelihood that the two documents will become out of sync. By way of illustration, the Business Code refers to the "Global Chief Compliance and Ethics Officer," while the Pharmacy Code refers to the "Global Chief Compliance and Privacy Officer."[1104] Although they both date to 2017, they are already out of sync with one another. It simply is not leading practice and should not happen especially when the documents are part of a crucial government commitment, such as a Corporate Integrity Agreement.

B. Organization

Like the separate Codes of Conduct, there is no apparent linkage between those responsible for controlled substances compliance and the Chief Compliance Officer's team. Walgreens 2008 CIA specified that the Compliance Officer "shall be a member of senior management of Walgreens, shall make periodic (at least quarterly) reports regarding Federal health care program compliance matters directly to the Audit Committee of the Board of Directors of Walgreens, and shall be authorized to report on such matters to the Audit Committee of the Board of Directors at any time," but "not be or be subordinate to the General Counsel or Chief Financial Officer."[1105] However, a 2012 chart showing Walgreens Corporate Organization does not show the Chief Compliance Officer as a direct report of Walgreens President and CEO, Greg Wasson.[1106] In fact, the Corporate Compliance function is not specifically listed on the chart.

On the same Corporate Organization chart, Compliance and Loss Prevention are shown under the Human Resources Division.[1107] From this chart, it is unclear whether "compliance" encompasses the Chief Compliance Officer's function but placing Compliance and Loss Prevention under the Human Resources professional staff function is both unusual and I believe a clear indicator that Walgreens did not value these functions sufficiently.

Likewise, Walgreens placed the Pharmaceutical Integrity Department many layers down in the organization under the Pharmacy Operations branch of the Health and Wellness business unit is a clear indication that the department is viewed by Walgreens senior management as relatively unimportant.[1108] Situated where it was in a business unit, Pharmaceutical Integrity had no meaningful organizational connection either with the Corporate Compliance department or the Corporate legal team, both of whom reside under the professional staff functions. Therefore, it follows the prior discussion that Walgreens viewed controlled substances compliance as

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[1103] *Id.* at 2-3.

[1104] *See* Business Ethics Code at 31; Pharmacy Code 2017 at 6.

[1105] *See* Walgreens 2008 CIA at § III.A.

[1106] *See* Org. Chart, Walgreens Corporate Organization (Jun. 5, 2012); WAGMDL00387629.

[1107] *Id.*

[1108] *See* Rex Swords CV (undated), P-WAG-02115 (Swords Deposition Exhibit 1).

an inventory management function (pharmacy operations) and not a true compliance function: "[t]hey would review and monitor orders and dispensing habits of the pharmacy … [s]o they were supporting the stores."[1109]

13.4.3 Walgreen's failures to designate a "high-level" individual or group with sole responsibility for controlled substances compliance or provide enough resources for the group contributed to its ineffective and dysfunctional anti-diversion program.

A. Prior to September 2012

Prior to 2012, responsibility for controlled substances compliance by the distribution centers was not vested in a single group or department, but it was spread across multiple departments as Walgreens represented in an organization chart from mid-2012. [1110] At that time, the SOM team was made up of members from Rx Purchasing, Logistics, Legal, Loss Prevention, & Store Order System IT.[1111]

Not only was responsibility divided among a group, but the group leadership or "ownership" for controlled substances compliance was in dispute. In April 2012, Ed Svihra, Director of Healthcare Loss Prevention wrote:

> To clarify, **Loss Prevention has not been responsible for reporting and taking action with district supervision since January 2011** as you state in your email. We did agree to assist with the analysis and design of the reporting. The Rx Purchasing team still has the responsibility to ensure the proper balance between in-stock condition, while limiting excess on-hand quantities. When the [CS-SOMS] pilot is initiated next month, the role of Loss Prevention will be to address those individuals at store level that may be consistently attempting to manipulate the system to increase orders of controlled substances and pseudoephedrine.[1112]

To which, Denman Murray, Director, Rx Inventory Management Drug Stores, responded, "[t]he Suspicious Order program prohibits ordering of controlled substances outside of tolerance limits. **LP [Loss Prevention] is responsible for monitoring the Suspicious Ordering dashboard**."[1113] Likewise Barbara Martin, Manager of Pharmacy Inventory Control under Mr. Murray, maintained that although she was involved with the SOM team and the program beginning in late 2008, she only provided general input on the inventory flow and data in flagged reports, but was not responsible for interpreting the data or taking any action on them.[1114]

According to Ms. Martin, the ownership issue ultimately came down to budgets:

[1109] *See* Rex Swords Deposition, 62:18-22 (Dec. 21, 2018).

[1110] *See* Walgreens Presentation, *Walgreen Co. Controlled Substance Anti-Diversion and Compliance Program,* (July 17, 2012) (from speaker's notes) WAGMDL00659802 at WAGMDL00659818.

[1111] *Id*

[1112] *See* Email from E. Svihra to M. Bleser, *et al.*, Update – Response From Healthcare LP (Apr. 9, 2012), (emphasis added) WAGMDL00580316.

[1113] *See* Email from D. Murray to M. Bleser and B. Martin, RE: Update-Response From Healthcare LP (Apr. 9, 2012) (emphasis added), WAGMDL00580316.

[1114] *See* B. Martin Deposition at 23:20 to 24:3, 74:16-20, 78:1-18 (Jan. 25, 2019).

> when you have a number of different teams working on a project like this where we have LP and legal and our group, it just comes down who wants to be the ones to put the money in their budget to have to pay for it.[1115]

Therefore, by defusing responsibility and accountability to an informal working committee, Walgreens abrogated its responsibilities to maintain and operate an effective anti-diversion program thus demonstrating a lack of commitment to controlled substances compliance, as well as poor corporate governance.

B. Formation of the Pharmaceutical Integrity Department

It was not until late 2012 with the formation of the Pharmaceutical Integrity Department under the direction of Rex Swords and Natasha Polster that Walgreens started vesting responsibility for controlled substances in a single group.[1116] The Department was created in response to the September 2012 Jupiter OTC and ISO in order " to convince DEA that the proposed penalty is excessive."[1117] However, despite the seriousness or the urgency of the situation, Walgreens failed to provide that organization with the authority and resources to effectively operate its anti-diversion program.

As previously discussed, the Pharmaceutical Integrity Department was effectively buried in the pharmacy operations function within Walgreens.[1118] Thus it lacked the necessary authority to administer the SOM program or to effect change.

Consistent with this lack of authority, Walgreens failed to resource the function appropriately to meet the demands of operating and maintaining the SOM program. Although a December 2012 pilot of the new automated SOM system revealed that there might be more than 14,000 "flagged" or suspicious orders generated per week,[1119] the Pharmaceutical Integrity Department numbered less than 5 FTEs.[1120] At its height, it numbered 11 FTEs.[1121] Taking into account the anticipated workload of "flagged" orders alone, Walgreens severely under-resourced the department setting it up for failure. Two years later Walgreens was no longer self-distributing controlled substances, and the SOM part of Pharmaceutical Integrity's distribution center SOM mission was moot.

[1115] *Id.* at 154:11-15.

[1116] *See* N. Polster Deposition at 14:21 to 15:17.

[1117] *See* Email from T. Polster to D. Doyle, FW: Proposed org chart, at 2 (Dec. 16, 2012) (Doyle was Vice President of Finance), WAGMDL00659270.

[1118] See above at section 8.3.1(B)(2).

[1119] *See* Email from T. Polster to D. Doyle, FW: Proposed org chart, at 2 (Dec. 16, 2012)

[1120] *See* N. Polster Deposition at 240:3-8.

[1121] *Id.* at 240:9-15.

13.5 Program Core – Requirements, Education, Detection & Corrections

13.5.1 From 1998 to 2014, Walgreens operated an anti-diversion program that lacked the fundamental controls of even a foundational compliance program.

From 1998 to 2009, Walgreens represented that the company had an effective anti-diversion program, however, Walgreens cannot demonstrate that it had even rudimentary suspicious order controls in place during that timeframe. This was highlighted by the Walgreens Internal Audit function in 2008 during an audit of DEA Compliance at the Perrysburg Distribution Center.[1122] The auditors uncovered system-wide deficiencies involving "suspicious controlled drug order processing and reporting," "controlled drug reporting specifically receiving record information," and a "lack of formalized CII controlled substance policies and procedures."[1123]

Beginning in 2009, "the Company … enhanced its suspicious order monitoring program for controlled substances in an effort to convince DEA that the proposed penalty is excessive and that our new processes will ensure that similar incidents do not recur.[1124] While it is true that by 2009 Walgreens began devoting more effort, including some additional resources, towards designing, operating and maintaining its SOM process and anti-diversion program, that effort failed to create either an effective or even credible program for controlled substances compliance. This was a systemic breakdown, and Walgreens in virtually every program core area examined was unable to produce verifiable evidence to support its claim that it was operating a credible anti-diversion program.

A. Written Standards

1. Handing Suspicious Drug Orders

The Handling Suspicious Drug Order "policy," which dates to 1998, was the earliest applicable document produced describing controlled substances compliance requirements,.[1125] From 1998 to 2012, this appears to be the main governance document for Walgreens' controlled substance program.[1126] Walgreens also admitted it did not have documentation resembling a policy and procedure manual for suspicious orders or diversion prevention.[1127] Instead, Walgreens relied on a series of emails, presentations and other informal, uncontrolled documentation such as business requirements documents to detail its compliance efforts.[1128]

[1122] *See* Memorandum from L. Dettmer*, et al.* to S. Kneller and D. Coughlin, DEA Compliance – Perrysburg Distribution Center (Dec. 22, 2008); WAGMDL00757148 at WAGMDL00757163 [Perrysburg DC Audit].

[1123] *Id.*

[1124] *See* Email from T. Polster to D. Doyle, FW: Proposed org chart, at 2 (Dec. 16, 2012) (Doyle was Vice President of Finance), WAGMDL00659270.

[1125] *See* Walgreens, *Handling Suspicious Orders* (Feb. 15, 2005) (the revised policy notes that it originated on Sept. 8, 1998), WAGFLDEA00001854 and WAGFLDEA00001855.

[1126] *See* E. Bratton 30(b)(6) Deposition at 44:24 to 45:7.

[1127] *See* E. Bratton 30(b)(6) Deposition at 25:20-24.

[1128] *See id.* at 53:18-20 ("Three e-mails and one policy section.").

In July 2012, Walgreens claimed to have several policies and procedures to combat diversion.[1129] Walgreens identified those written standards as the:

- Code of Conduct,
- Controlled Substances Prescriptions and Good Faith Dispensing Policy,
- Controlled Substances Pick Up and Inventory Policies and Procedures,
- Customer Authentication Policy, and
- Handling Suspicious Drug Orders Policy.[1130]

Of those listed standards, only the Code of Conduct, Customer Authentication and Handing Suspicious Drug Orders standards applied to its Distribution Centers.[1131]

This lack of documentation not only was contrary to the requirements for credible controlled substances and corporate compliance programs, it was contrary to industry guidelines as well. HDMA, in its 2008 voluntary industry guidelines, "recommended that, to implement these Industry Compliance Guidelines, **specific written company SOPs** be developed and maintained."[1132] However, other than this single policy governing controlled substances compliance, my review uncovered nothing else resembling a policy or procedure.

The Handling Suspicious Drug Order "policy" was remarkable for its brevity and does not meet even the most basic anti-diversion requirements.[1133] It also failed to provide enough specifics to direct Walgreens staff members on what they were supposed to do.

For example, the "policy" stated that the Logistics and Planning Department sent Suspicious Order Reports to the Distribution Centers.[1134] The Distribution Centers were to file the reports for five years and make loss and theft reports to the DEA using DEA Form 106.[1135] However, beyond the generic organizational designations, the "policy" did not outline, who specifically within the Logistics and Planning Department or the Distribution Centers was responsible for ensuring Suspicious Order Reports are sent, filed, and any necessary reports made to the DEA. Nor was there any indication of who authored or approved the document.

The "policy" also did not outline the criteria the Logistics and Planning Department used to determine an order was suspicious. Key terms such as "unusual size" and "unusual frequency" were undefined in the document. It did not even incorporate the DEA regulatory requirements by reference to allow a staff member to research the DEA's definitions of those terms.

[1129] *See* Walgreens Presentation, *Walgreen Co. Controlled Substance Anti-Diversion and Compliance Program,* 5 (July 17, 2012) WAGMDL00659802.

[1130] *Id.*

[1131] *Id.*

[1132] *See* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 14 (2008) (emphasis added), WAGMDL00673706 at WAGMDL00673708.

[1133] *See* Walgreens, *Handling Suspicious Orders* (Feb. 15, 2005). The text of the policy is reproduced in Appendix G at Figure 1.

[1134] *Id.*

[1135] *See id.*

The Distribution Center filing requirements also did not adhere to the basic controlled substances requirements in force at that time. According to the "policy," the Distribution Centers were only required to notify the DEA about substantial losses or thefts. It did not mandate that the Distribution Center report all suspicious orders to the DEA field office.[1136]

Also, in contravention to accepted compliance practice at the time[1137] and specifically highlighted by the DEA in 2012,[1138], there was no requirement that Distribution Centers investigate the circumstances reported to it by the Logistics and Planning Department or take any affirmative action to prevent further losses, thefts, or suspicious orders such as holding current or even future orders to those customers. Therefore, the "policy" failed to mandate what should occur when the Distribution Center encounters "suspicious orders" that did not rise to the level of a substantial loss or a theft.

In April 2012, the Handling Suspicious Drug Orders "policy" was amended to include the following statements:

> Effective calendar year 2012, the Controlled Substance Order Monitoring and Prevention System prevents suspicious control drugs from being shipped to the stores. In calendar year 2012, because of the program mentioned, suspicious control drug reports are no longer generated as their shipment is prevented by the system.[1139]

Like the prior 1998 and 2005 versions, the updated 2012 version of the "policy" did not mandate that the Distribution Center report all suspicious orders to the DEA field office.[1140] Nor, did it require the Distribution Centers to investigate the circumstances reported to it by the Logistics and Planning Department or to take any affirmative action to prevent further losses, thefts, or suspicious orders such as holding current or even future orders to those customers. All that was required was for the Distribution Centers to notify the DEA about substantial losses or thefts. Therefore, the amended "policy" still did not meet even the most basic anti-diversion requirements of the DEA.

2. Pharmacy Code

Walgreens' Pharmacy and Health Care Code of Conduct Policy (Pharmacy Code), originally enacted in 2008, applied to all employees working in any pharmacy or pharmacy operations, including those handling-controlled

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[1136] *See* 21 C.F.R. § 1301.74(b).

[1137] *See* Letter from Wendy Goggin to John Gray (Oct. 17, 2008) WAGMDL00673706. At the time, Ms. Goggin was DEA Chief Counsel and Mr. Gray was President and CEO of the Healthcare Distribution Management Association. The letter discusses HDMA's voluntary industry guidelines, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances."

[1138] Letter from J. Rannazzisi to All Registrants (Jun. 12, 2012).

[1139] *See* Walgreens, *Handling Suspicious Orders* (Apr. 4, 2012), WAGFLDEA00000027.

[1140] *Id.*

substances.[1141] Employees were expected to acknowledge their understanding and commitment to the Code annually and it was an element of their performance reviews.[1142]

The Code, itself, specifically addressed controlled substances providing:

> Walgreens is committed to complying at all times with all applicable controlled substances laws and regulations. Pharmacy and other health care team members must read and be familiar with Walgreens Policies and Procedures for a more detailed explanation of such requirements. Distribution center team members must read and be familiar with Walgreens Procedure Manual, CM-15 (Distribution Center Procedures for Handling Controlled Drugs).[1143]

The Code also stated that "Walgreens is committed to cooperating with law enforcement officials consistent with company policy and with its obligations under applicable state and federal law" and that:

> Walgreens WILL NOT TOLERATE an illegal, unprofessional or unethical act by any team member, INCLUDING, BUT NOT LIMITED TO, THE UNAUTHORIZED SALE, POSSESSION, USE OR DIVERSION OF CONTROLLED SUBSTANCES. Team members who divert, or illegally possess, sell, or use controlled substances, or fail to report drug diversion, will subject themselves to state or federal prosecution and disciplinary action up to and including termination, Team members should bear in mind that violating any Controlled Substances Act can lead to arrest, prosecution and/or disciplinary action by the state board of pharmacy, including fines, probation, suspension or revocation of license.[1144]

Employees were obligated to report, in a timely manner, violations of the Code, Walgreens policies and procedures, and diversion including "any suspicious activities involving controlled substances."[1145] Although this appeared robust on paper, with Walgreens paucity of policies and procedure, lack of training and no definition of "any suspicious activities involving controlled substances," it was unlikely to be triggered in the case of controlled substances and thus was ineffective.

3. Customer Authentication Policy

Dating to late 2009, the Customer Authentication Policy outlined the Walgreens pharmacy authentication process, a component of Know Your Customer. The one-page policy had only three main requirements:

- Ensure customers have a valid license from the State Board of Pharmacy and the DEA;

[1141] *See* Walgreens, Pharmacy and Health Care Code of Conduct Policy, (May 2011) (The origination date of the Pharmacy Code was July 23, 2008), WAGFLDEA00000347.

[1142] *Id.*

[1143] *See* Walgreens, *Walgreens Pharmacy and Health Care Code of Conduct and General Training*, 1 (May 6, 2011), WAGFLDEA00000127; *see also* Walgreens, *Walgreens Pharmacy and Health Care Code of Conduct and General Training*, 1 (June 6, 2012), WAGMDL00444056. Since the document contains no revision history indicating what changed, it appears that Walgreens made only minor changes between the 2011 and 2012 versions.

[1144] *Id.* at 1-2 (emphasis in the original).

[1145] *Id.* at 2.

- Ensure subsequent orders for controlled substances are "regularly and systematically reviewed ... [and] that such orders are consistent with and reasonable for that particular pharmacy's book of business;" and
- Make sure that "[o]rders which may fall outside the usual and customary scope for that particular pharmacy are automatically reduced, identified via an exception report and subject to additional review."[1146]

Like the Handling Suspicious Orders policy, this policy lacked specifics on how the process works, as well as who was subject to it and had responsibilities under it. In short, as a policy or a procedure, it was deficient and failed to meet even basic compliance standards and expectations.

4. Pharmaceutical Integrity Department SOPs

There was some evidence that the Pharmaceutical Integrity Department attempted to create some written standards resembling SOPs. For example, there was a nine-page document entitled "Suspicious Order Monitoring Program Policy and Procedures for the Pharmaceutical Integrity Team."[1147] However, it was unclear when this document was effective and who approved it.

While it did describe in a detailed manner how to pull reports from the various automated systems and use the central monitoring and control dashboard, it was vague on the criteria for how that information was reviewed or how further investigations were undertaken, leaving it to staff members to use "their professional judgment and pharmacy operations experience," but stated "unusual trends in historical data" or "patterns in drug families in certain markets or communities" should be escalated.[1148] However, none of these vague parameters were defined in the document. Therefore, it was deficient on its face as a SOM policy or procedure.

B. Detection & Corrections

1. Order Monitoring Controls

From 1998 to 2009, Walgreens claimed Distribution Center personnel were monitoring suspicious orders and that those personnel used a variety of tools. However, the evidence supporting both the active monitoring of orders and the use of specific tools is at best sketchy.

At the outset, it is unclear exactly what role Walgreens expected its distribution centers to fulfill under the SOM and anti-diversion programs. On the one hand, Edward Bratton noted that distribution centers "are an important part of our system to detect and monitor controlled substances ordering."[1149] On the other hand, a 2012 Walgreens presentation describing Walgreens's program stated:

> Distribution Centers are not **designed to be a backstop to the pharmacists** who are the front lines; rather, Distribution Centers are **more akin to supply warehouses**. The stores, on the one

[1146] *See* Walgreens, Policy & Procedure Customer Authentication, § 4 b,d,e (Apr. 2, 2012), WAGFLDEA00001746.

[1147] *See* Walgreens, *Suspicious Order Monitoring Program Policy and Procedures for the Pharmaceutical Integrity Team,* (undated); WAGMDL00395923 at WAGMDL00395928.

[1148] *Id.* at 9.

[1149] *See* E. Bratton Deposition at 119:8-10.

hand, and corporate headquarters, on the other hand, are best equipped to ensure compliance and assist in combatting controlled substance abuse.[1150]

Walgreens described three different tools utilized from 1998 to 2009:

- **RX Questionable Order Qty** – This process was performed by the distribution center personnel. The procedure called for distribution personnel to review orders and contact the pharmacy if there was a "questionable quantity".[1151] There was no criteria provided about the levels, no outline of what investigations occurred, and no copies of the reports were provided during discovery.[1152]
- **"Pickers"** – This control involved relying the employees in the controlled substances vault to identify potentially suspicious orders.[1153]
- **Chemical Handler's Reports** – These reports "flagged" potentially suspicious orders after applying the "3x" multiplier from the Chemical Handlers Manual.[1154] There was no discussion of holding and investigating "flagged." The reports simply identified orders over the limit, which were collected and simply sent to the DEA. These reports were stopped when the CSOM system was deployed.[1155]

Of the three tools, the Chemical Handler's Reports generated many suspicious orders. For Ohio alone, there were 5,500 suspicious orders from 2006 to November 2012.[1156] None of these shipments were properly investigated or stopped.[1157]

Neither the excessive quantity query nor the Chemical Handler's Report froze "flagged" orders or prevented them from ultimately shipping.[1158] Even when suspicious orders were identified, I saw nothing documented that suggested that Walgreens did more than a cursory further inquiry before the order shipped.[1159] Walgreens also admitted that the company is unaware of any due diligence occurring on orders flagged by the Chemical Handler's Report.[1160]

[1150] *See* Walgreens Presentation, *Walgreen Co. Controlled Substance Anti-Diversion and Compliance Program,* (July 17, 2012) WAGMDL00659802 at WAGMDL00659817 (emphasis added) (see speaker's notes).

[1151] *See* E. Bratton 30(b)(6) Deposition at 83:11-15; *see also*, Walgreens, Rx Questionable Order Qty Procedure, (Dec. 11, 2006), WAGMDL00757788. The procedure was modified in 2010 and again in 2013, when among other things, the name was changed to "Authentication of Prescription Order Policy." *See* WAGMDL00751822; WAGMDL00749381.

[1152] *Id.* at 85:11-23 and 95:11-14.

[1153] *Id.* at 113:20 to 114:5; *see also*, Walgreens, Rx Questionable Order Qty Procedure, (Dec. 11, 2006), WAGMDL00757788. The procedure was modified in 2010 and again in 2013, when among other things, the name was changed to "Authentication of Prescription Order Policy." *See* WAGMDL00751822; WAGMDL00749381.

[1154] *See* E. Bratton 30(b)(6) Deposition at 144-22-24; *see also* Discussion *infra*.

[1155] *See* E. Bratton 30(b)(6) Deposition at 150:2-5.

[1156] *Id.* at 164:19-22.

[1157] *See* Errata to Ed Bratton 30(b)(6) Deposition, Erratum No. 3.

[1158] *See* E. Bratton Deposition at 65:20 to 66:11 and 181:18 to 182:3.

[1159] *Id.* at 95:11-14 and 159:20-24; *see also* Jupiter Show Cause Order at ¶¶11-12.

[1160] *See* Errata to Ed Bratton 30(b)(6) Deposition, Erratum No. 3.

2. Automated Controlled Substance Reporting (CSOM System)

Starting in 2009, Walgreens began work to develop an Automated Controlled Substances Reporting ("CSR") system "to identify and reduce excessive orders."[1161] Work on the new system was divided into five phases, with Phase 5 being deployed in November 2012, more than three years after the start of Phase 1.[1162] During this "gap" before the new system deployed, Walgreens was not meeting its anti-diversion requirements as the DEA outlined in great detail in the Jupiter OTC and ISO.[1163]

The new system, later renamed the Controlled Substance Order Monitoring system or CSOM, was conceived to be the primary mechanism to monitor, detect, and report suspicious orders. While it was "a bolt-on" system to the strategic inventory management system ("SIMS"),[1164] it was considered the centerpiece of the Walgreens distributor anti-diversion program. However, as designed and implemented, the CSOM system failed to achieve that objective.

3. The Bancroft Algorithm

The heart of CSOM system was an algorithm developed by Wayne Bancroft and Tracy Morris in 2008.[1165] As originally conceived in 2008, the Bancroft algorithm was "a methodology for identifying suspicious orders in terms of order size and order frequency."[1166] Order size and order frequency were two of the three DEA listed criteria for determining if a controlled substances order was "suspicious."[1167] The regulation also made clear that the three DEA criteria are not the only ones that could render an order as "suspicious."[1168]

The CSOM system deployed in November 2012 used the algorithm from two dimensions – tolerance and ceiling.[1169] The tolerance was the number of bottles ordered above the store's average historical orders based on the last 26 weeks of ordering history.[1170] The ceiling was based on stores with similar volume when compared to the previous six (6) weeks.[1171] According to the algorithm proposal, "[i]f an order is placed on the

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[1161] *See* Walgreens Presentation, *Controlled Substance Ordering – Evolution of Controlled Substances Ordering Process*, 3 (Oct. 11, 2012) (the system later came to be known as the Controlled Substance Order Monitoring and Prevention System), WAGMDL00667936 at WAGMDL00667938. ["Evolution Presentation"]; *see also* Appendix G at Figure 2.

[1162] *Id.*

[1163] *See generally* Jupiter Show Cause Order.

[1164] *See* D. Murray Deposition at 35:20-21.

[1165] *See* Memorandum from W. Bancroft and T. Morris to S. Bamberg, *et al.* DEA Suspicious Order Reporting, 1 (Jun. 23, 2008) (Since Bancroft was the Lead Business Systems Analyst, IT Integration and the mathematical lead, the algorithm has become associated with his name**)**, WAGMDL00624503 ["Bancroft Algorithm Proposal"].

[1166] *Id.* at 1.

[1167] *See* 21 C.F.R. § 1301.74(b). The third enumerated criterion was a substantial deviation from a normal ordering pattern.

[1168] *Id.* The regulation specifically states that suspicious orders "include" these three criteria clearly indicating that these listed criteria were not a fixed set.

[1169] *See* Evolution Presentation at WAGMDL00667940.

[1170] *Id.* at WAGMDL00667943.

[1171] *Id.* at WAGMDL00667943

DC [Distribution Center] that exceeds its tolerance limit the order is flagged as suspicious."[1172] The final system was being developed to simply reduce orders to whichever dimension yields the lowest value.[1173]

Although first deployed in August 2009 as a pilot program, the CSOM system underwent many changes through 2014.[1174] These changes overall did not serve to enhance the system, but rather to weaken it.

Despite the apparently advanced algorithm employed by the CSOM system, Walgreens anti-diversion program was plagued by "loopholes" that effectively negated the value of the algorithm and the system.[1175] Furthermore, these "loopholes" allowed Walgreens to avoid its obligations, in some cases intentionally and systematically, to report suspicious orders and prevent diversion. Therefore, overall the CSOM system essentially became useless as an anti-diversion control.

4. CSOM "Loopholes"

a. Order Intercept (a.k.a. "Cutting" Orders)

One major loophole in the system involved order intercepts or ordering "cutting." Rakesh Khanna from Store Replenishment and Forecasting described how the order intercept process worked in a memorandum she wrote and circulated in October 2011.[1176] While explaining the business reason for addressing suspicious orders, Ms. Khanna wrote:

> The purpose of this project [to intercept orders] is to create a process to systematically identify and prevent suspicious orders based on a formula used to determine inconsistent (suspicious) ordering patterns for controlled drugs. Any Control Drug Orders that are deemed suspicious will be flagged as suspicious and populated in a file to be sent up centrally to Loss Prevention and Rx services for review/analysis. The order that is flagged as suspicious on the store side will be intercepted and the order qty will be reduced to a non-suspicious (order limits) level. **The item will be reduced to a non-suspicious level <u>in order to prevent suspicious orders from being sent over to the DC</u>. This method will help to insure [sic.] that <u>the DC does not receive suspicious orders from stores</u> and limit the possibility of fines that may be imposed by the DEA.**[1177]

Thus, although the CSOM system was designed to flag store orders that exceeded the tolerance or ceiling limit for a particular scheduled product at the distribution level, the plan now was to intercept orders that fit the definition of "suspicious," and thus need further investigation and potential reporting to the DEA, and render

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[1172] *See* Bancroft Algorithm Proposal at 1.

[1173] *See* Evolution Presentation at WAGMDL00667943.

[1174] *See* Appendix G at Figure 2.

[1175] *See* N. Polster Deposition at 157:9-18.

[1176] *See* Email from R. Khanna to K. Provost, *et al.*, DEA Business Reason (Oct. 27, 2011); WAGMDL00119542.

[1177] *See* Email attachment *DEA Intercept Suspicious Order* from R. Khanna to K. Provost, *et al.* at 1 (Oct. 27, 2011) (emphasis added); WAGMDL00119542 at WAGMDL00119543; *see also* Memorandum from T. Polster to R. Swords, *Status* (Nov. 30, 2012) (Under the SOM Meetings section it reads "[w]ork group has been put together to begin the determination between a suspicious order and an order of interest."), WAGMDL00574824 at WAGMDL00574825.

them "non-suspicious." By altering ("cutting") the orders during transmission from store to distribution center, the distribution center would receive an order that was not "flagged" and thus, Walgreens's position was, the DC would not be required to take any action beyond filling the order. This would reduce the number of orders needing investigation from hundreds per week to a more manageable level.[1178] However, by taking this approach, Walgreens intentionally and systematically avoided its obligations to investigate and report suspicious orders and prevent diversion.

b. "Flagged" Orders Are Not "Suspicious Orders"

A second major loophole involved the Pharmaceutical Integrity department's interpretation that orders exceeding the ceiling limit and flagged by the system using the Bancroft algorithm were not suspicious. Orders that exceeded the tolerance limit were "flagged [by the system] as suspicious,"[1179] and under the controlled substances regulations, suspicious orders are to be investigated and reported "when discovered."[1180]

The Walgreens Pharmaceutical Integrity Department as of 2012, took the position that "flagged" orders were not "suspicious" as defined by DEA regulations because:

> Whether it was suspicious or not did not even come into play because we had an algorithm and we told them that they weren't supposed to go over it and if they needed to go over it, they had to supply the necessary information so that we could have the documentation we needed.[1181]

As Ms. Polster further elaborated, an order "flagged" by the system was not considered "suspicious" because she "never felt like any pharmacy manager or pharmacist was doing anything nefarious to get more product into the store."[1182] At the outset, although the DEA provides regulatory latitude to include another criterion to classify an order as "suspicious," the feeling that "no pharmacy manager or pharmacist was doing anything nefarious to get more product into the store,"[1183] is neither an objective nor valid gauge, for determining whether an excessive order is suspicious and diversionary.

Ms. Polster also stated that orders "flagged" using the Bancroft algorithm were simply "an order that was over the algorithm that was designed for that specific store and that it did not conform to … what we thought the store needed. "[1184] Therefore, since the order did not ship in full, it was not deemed "flagged,"[1185] not deemed an "order of interest," and not deemed "suspicious."[1186]

[1178] *See* Email from T. Polster to D. Doyle, FW: Proposed org chart, at 2 (Dec. 16, 2012) (Doyle was Vice President of Finance), WAGMDL00659270. The December 1-8, 2012 test of the CSOM system produced 470 "cut orders." *Id.*

[1179] *See* Bancroft Algorithm Proposal at 1.

[1180] *See* 21 C.F.R. § 1301.74(b).

[1181] *See* N. Polster Deposition. at 174:3-8. See section on Controlled Substances Overrides below for a discussion of the "necessary information."

[1182] *Id.* at 175:8-10.

[1183] *Id.* at 175:8-10.

[1184] *Id.* at 175:15-16.

[1185] *Id.* at 187:5-9.

[1186] *Id.* at 221:11-21.

Although this was merely a game of semantics, the impact was real. Orders flagged using the Bancroft algorithm were in fact "suspicious," in accordance with the plain meaning of the word, and therefore needed further investigation and potential reporting under the DEA's requirements. During the week of December 1-8, 2012, the CSOM system in "tracking mode" generated more than 14,000 potential ceiling limit "orders of interest" and "[e]ach order of interest has to be investigated before more product can be added to the store."[1187] So there was a real concern that once fully operational the CSOM system could generate "thousands of 'orders of interest' per week."[1188] At the time, Walgreens understood there was direct correlation between how much they decreased a ceiling level and the amount of work (number of flagged orders) that reduction generated.[1189] Walgreens's contention that because it deemed these "flagged orders" not to be either "of interest" or "suspicious" that these orders were then not "suspicious" for purposes of further investigation or DEA reporting is both specious and non-compliant.

c. Use of Outside Distributors & Visibility to Order Ceilings

As originally implemented, the CSOM system allowed Walgreens stores to order up to their ceiling limits as determined by the Bancroft algorithm. If a Walgreens store hit the store ceiling limit or tried to exceed it, the order was not shipped. This process of simply not shipping an order that exceeded the threshold meant that the store only knew there was a problem when the order failed to arrive.[1190]

From 2009 to 2012, the CSOM system only reviewed store orders placed with the Walgreens distribution centers.[1191] Therefore, if a store's order of controlled substances failed to arrive, they could place an order with an outside distributor, such as Cardinal Health or AmerisourceBergen, and "so they ordered it through the wholesaler [outside distributor]."[1192]

Pharmaceutical Integrity did not view this situation as a "loophole" but rather as a situation of poor communication "between the support center and the stores to let them know that they've reached the limits we set for them."[1193] and "[t]he wholesaler has their own suspicious order responsibilities."[1194]

As a result of the poor job "of communicating to the stores why they didn't get their order,"[1195] a relatively late adjustment to the system was made to provide stores visibility to their order ceilings.[1196] Therefore, as Ms. Polster described it:

[1187] *See* Email from T. Polster to D. Doyle, FW: Proposed org chart, at 2 (Dec. 16, 2012), WAGMDL00659270.

[1188] *Id.* at 1.

[1189] *See* Email from T. Polster to S. Mills, RE: Ceiling Update, (Jan. 4. 2013), WAGMDL00414048.

[1190] *See* N. Polster Deposition at 169:1-7.

[1191] *See* Walgreens Presentation, *Controlled Substances Talking Points*, 2 (Jun. 12, 2012), WAGMDL00077016 at WAGMDL00077017.

[1192] *See* N. Polster Deposition at 250:15-16.

[1193] *See id.* at 253:4-7.

[1194] *Id.* at 250:16-17.

[1195] *See id.* at 252:11-12.

[1196] *See id.* at 167:20 to 168:22.

> We had to train the stores, leave your orders alone. Let the orders generate by themselves based on the algorithm and if you feel that you need more, fill out the controlled substance override form so that we can look at it, make sure we have proper documentation as to the reason why you need it, and then we will place the order for you.[1197]

Sometime in late 2013 or early 2014, Walgreens implemented a solution that allowed the stores to see how many bottles remained before the ceiling was triggered. With that information, if the stores needed more inventory than what the system allowed, they could order directly from the outside wholesaler rather than fill out a Controlled Substances Override Form.

In the case of Walgreens stores ordering from Cardinal, Cardinal at least by January 2013, was supplying Walgreens with a list of all stores that were within 75% or more of their monthly Cardinal accrual to, as Steve Mills put it, "help us [Walgreens] prevent a SOM from occurring."[1198]

d. PDQ Orders & "Inter-storing"

Another "loophole" in the CSOM system involved PDQ orders.[1199] These orders allowed a store to place orders for drug products, including controlled substances, that were needed quickly. Prior to October 2012, Walgreens stores could order oxycodone via the PDQ process once they hit their ceiling limit. PDQ orders were not included in the monthly cumulative limits and therefore, "a store could hit the line limit on their weekly CII whs order and then they could create a PDQ order on a daily basis and far exceed the monthly line limit total we were trying to enforce."[1200]

By October 2012, oxycodone PDQ orders were no longer allowed and "[b]y turning these items off of PDQ, the only way for a store to exceed the line limit is for us to put in a manual order. Hence, the Control Substance Order Override Form."[1201]

Although the PDQ avenue was blocked, Kermit Crawford, President of Walgreens Health and Wellness pointed out that a store could simply do an interstore transfer.[1202] Until early 2013, interstore transfers occurred with no visibility by Pharmaceutical Integrity.[1203] However, according to Ms. Polster, interstoring was controlled via the controlled substances invoicing process that required knowledge by Walgreens leadership.[1204] However,

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[1197] *See id.* at 169:9-16.

[1198] *See* Email from N. Rausch (Cardinal Health) to P. Holohan (Cardinal Health), RE BW6664381WALGREEN CO. (Jan. 21, 2013), CAH_MDL2804_00783520; *see also* Email from S. Mills (Walgreens) to P. Holden (Cardinal Health), RE BW6664381WALGREEN CO. (Jan. 18, 2013) (embedded in N. Rausch thread), CAH_MDL2804_00783520.

[1199] While no official definition of "PDQ" was found, according to Natasha Polster to her it meant "pretty darn quick." *See* N. Polster Deposition at 253:21-24.

[1200] *See* Email from D. Lovejoy to K. Crawford, *et al.*, FW: OXYCODONE no longer being ordered via PDQ (Oct. 1, 2012), WAGMDL00705321.

[1201] *Id.*

[1202] *See* Email from K. Crawford to D. Lovejoy, *et al.*, RE: OXYCODONE no longer being ordered via PDQ (Oct. 1, 2012), WAGMDL00705321.

[1203] *See* N. Polster Deposition at 257:14-16 and 258:1-2.

[1204] *Id.* at 257:21-24.

because interstore transfers avoided the CSOM system, the practice effectively undermined the anti-diversion program by allowing stores to secure amounts of controlled substances well in excess of the established CSOM ceiling amount.

Walgreens store 2865 in Modesto, California is a case in point. During a GFD (Good Faith Dispensing) audit in October 2012 it was noted that:

> **This store's average movement on hydro/APAP 10/325 is 17,500 tabs a week put them over the corporate limit**. This changed their ordering habits with Cardinal, which then led to an SOM with them. I submitted a report which was approved by WAG but denied by Cardinal. **As such this location has had a large increase in interstores. This increase in interstores has led to short supplies at other locations in town.** We need to get Cardinal back on shipping this location additional controls.[1205]

e. Removing Stores from the CSOM System

During Phase II of the CSOM project, Rakesh Khanna authored a project request estimate to give "Rx Services … the ability to remove items from the order limitation process or **remove an entire store from the order limit program for a limited amount of time**."[1206] An earlier project requirements document suggested this ability was being added "to account for stores that may need to order more of an item for a certain amount of time."[1207] In other words, to circumvent the SOM system.

This option continued to exist after the formation of Pharmaceutical Integrity allowing them to switch stores to "tracking" only.[1208] However, despite Ms. Polster's assertion that policies and procedures existed to govern this process and define "a limited amount of time," no supporting documentation was provided nor had Ms. Polster ever seen those policies and procedures.[1209] Therefore, it is a reasonable assumption that the documentation did not exist, especially given Walgreens overall poor documentation practices.

f. Controlled Substances Overrides

Beginning in 2013, Walgreens implemented the process of Controlled Substances Overrides ("CSO Overrides"). The goal of this process was to ensure there was "adequate review before sending in additional inventory" above the system generated ceiling (Bancroft algorithm).[1210] The change resulted because "[t]he previous system would continue to send additional product to the store without limit or review which made

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[1205] *See* Email from M. Federico to D. Murray, GFD Audit for store 286 in Modesto, California, 2 (Oct. 31, 2012) (emphasis added). WAGMDL00113808 at WAGMDL00113810. At the time Michael Federico was District 293 Pharmacy Supervisor and Denman Murray was Director of Rx Inventory Management Drug Stores.

[1206] *See* R. Khanna, *DEA Suspicious Order Item Limits – Phase II Project P-09002*, 1 (Aug. 26, 2009), WAGMDL00492067.

[1207] *See* Ora Yelvington, *Intercepted/Suspicious Store Orders Project#: P99999 Requirements Document Version 1.0*, 3 (Feb. 2009) WAGMDL00492626.

[1208] *See* N. Polster Deposition at 262:4-7.

[1209] *Id.* at 262:13 to 263:14.

[1210] *See* Email from E. Bratton to A. Patel, RE: Controlled Substance Order Quantity Override Form (Aug. 19, 2013), WAGMDL00021425.

possible the runaway growth of dispensing of products like oxycodone, that played a roll in the DEA's investigation of Walgreens."[1211]

However, when Walgreens examined the percentage of CSO Overrides that were approved versus those disapproved, they found that for FY 2014, 95.52% of the overrides submitted were approved which increased slightly to 95.63% in FY 2015.[1212] This is consistent with the previously discussed examples of Walgreens Stores 3314 and 12444.[1213] Therefore, as these data show, if a CSO Override form was submitted, it was almost guaranteed to be approved. Such high approval rates are not normal and demonstrate that Pharmaceutical Integrity simply was not conducting a robust interrogation and investigation of the information presented.

5. The Net Effect on the CSOM System

The net effect of the changes implemented to the CSOM system between 2009 and 2013 rendered the system essentially useless as anti-diversion control. In 2016, Walgreens prepared a "State of Rx Integrity" presentation examining data from FY 2014 and FY 2015 (October 2013 to October 2015).[1214]

From 2014 to 2015, the quantity of oxycodone dispensed across all Walgreens stores increased by 9% and the average quantity per prescription increased by 1.34% for 2014 and 1.96% for 2015.[1215] While the total quantity of hydrocodone sales decreased by 4%, the average quantity per prescription increased by 1.66% in 2014 and 5.43% in 2015.[1216]

Against this backdrop, Walgreens also examined the total population of "flagged" orders for FY 2014 and FY 2015, which appear on average to trend consistently at about 4,000 per month:[1217]

- **Above the Limit:** Orders exceeding the tolerance limit accounted for 74.16% for FY 2014 and 77.48% for FY 2015 of all "flagged "orders.
- **Below the Limit:** Orders reduced to below the tolerance or ceiling accounted for 25.74% for FY 2014 and 21.64% for FY 2015 of all "flagged" orders.

These data imply that Walgreens stores were routinely submitting orders that were "flagged" by the CSOM system and that once "flagged" they stood less than 1 in 4 chance of being reduced. However, for the other 75% of the orders, it is not clear whether they were shipped or simply were not filled.[1218] Notwithstanding Walgreens strained interpretation of what constituted a suspicious order, every "flagged" order either should

[1211] *Id.*

[1212] *See* E. Bratton Presentation, *State of Rx Integrity*, 22 (May 10, 2016); WAGMDL00010887 at WAGMDL00010888.

[1213] *See* Discussion *infra.*

[1214] *See* E. Bratton Presentation, *State of Rx Integrity* (May 10, 2016); WAGMDL00010887 at WAGMDL00010888.

[1215] *Id.* at 6.

[1216] *Id.* at 8. Fewer prescriptions with larger volumes would result in fewer sales.

[1217] *Id.* at 17.

[1218] *See* N. Polster Deposition at 332:23-334:3.

have been reported to the DEA as "suspicious" or subjected to further investigation to validate that the "flags" were false positives. By failing to do so, Walgreens' anti-diversion program was not effective.

C. Audits

While there is some evidence that Walgreens conducted audits of its controlled substances distribution centers, these audits seemed to be *ad hoc* events, rather than part of a normal, programmatic audit cycle. I saw no formal policies or procedures evidencing a programmatic approach to internal auditing of its distribution centers that Walgreens' Internal Audit Department employed.

When done, these audits highlighted significant flaws with Walgreens controlled substances compliance program.[1219] However, although the infrequent internal audit identified systemic shortcomings with Walgreens' controlled drug reporting process, the company failed to address the matters in a timely fashion. For example, in the case of the internal audit of the Perrysburg distribution center, the audit fieldwork was completed in November 2008,[1220] but Walgreens' management only committed to take up the problem in May 2009.[1221]

D. Education

There is scant evidence that Walgreens undertook any comprehensive efforts to train its employees, even ones in positions of substantial authority for controlled substances compliance, about the company's obligations surrounding controlled substances and the DEA's requirements. For example, Edward Bratton, Natasha Polster and Rex Swords all testified that before coming into their respective roles with responsibility for controlled substances compliance, they had operational but no legal or compliance background.[1222] They also received no formal training but received on-the-job support from Walgreens'' regulatory and legal staff members.[1223]

On the topic of general employee training, Mr. Bratton testified that he could not identify any specific employee training programs "about opiates and suspicious order monitoring."[1224] Furthermore, no training materials supporting such training programs were located.[1225]

[1219] *See* Internal Audit Report, DEA Compliance – Perrysburg Distribution Center, (Dec. 22, 2008), WAGMDL00757148 at WAGMDL00757163.

[1220] *Id.* at 2 (Background), WAGMDL00757162.

[1221] *Id*. at Summary of Findings, 2, WAGMDL00757160.

[1222] *See* E. Bratton Deposition, 17: 4-10 (Nov. 30, 2018) (discussing his full resume which was not produced) ["Bratton 11/30/18 Deposition"]; N. Polster Deposition at 16:2-10; R. Swords Deposition at 92-8-14.

[1223] *See* Bratton 11/30/18 Deposition at 51:8 to 54:1; N. Polster Deposition at 80:9-20; R. Swords Deposition at 96:1-4.

[1224] Bratton 11/30/18 Deposition at 138:24 to 139:8; *see also* B. Martin Deposition at 65:1-24.

[1225] *Id.* at 139:8-11.

13.6 Accountability - Consistent Enforcement

13.6.1 Walgreens failed to enforce the standards outlined in the Pharmacy Code and thus there is no real accountability for the program's lack of effectiveness.

Walgreens' Pharmacy Code mandated full compliance with the requirements pertaining to controlled substances distributors and obligate employees to report breaches of the Code.[1226] However, there was no evidence presented to demonstrate Walgreens enforced the standards in the Code, especially as it pertained employees in positions of substantial authority for controlled substances compliance.

The crucial employees, with responsibility for shaping, maintaining and operating Walgreens' anti-diversion program (e.g., Natasha Polster, Edward Bratton, and Rex Swords) continued in positions of substantial authority with Walgreens after the failure of its compliance program for controlled substances, and the cessation of internal distribution of Schedule II and III products to the retail locations. By failing to hold these individuals accountable for the controlled substances program's established lack of effectiveness, Walgreens' compliance program and its Pharmacy Code are merely words on paper that profess to hold culpable individuals accountable.

14 Mallinckrodt Pharmaceuticals

14.1 Background

Mallinckrodt Pharmaceuticals ("Mallinckrodt") began with the formation of G. Mallinckrodt and Company in 1867 by the three Mallinckrodt brothers, Gustavo, Otto and Edward to supply local pharmacists because it was the only chemical company west of Philadelphia.[1227] In 2000, Mallinckrodt was acquired by Tyco International's healthcare division, which became Covidien in 2007.[1228] Mallinckrodt Pharmaceuticals later split from Covidien in 2013 to become "an independent, $2 billion public company that develops, manufacturers, markets and distributes specialty pharmaceutical products and diagnostic imaging agents."[1229]

Mallinckrodt's publicly stated mission is "managing complexity, improving lives", which is centered around a set of four values: "patient-centric, integrity, innovative and collaborative."[1230] With over 3,600 employees

[1226] *See* Walgreens, *Walgreens Pharmacy and Health Care Code of Conduct and General Training*, 1-2 (May 6, 2011), WAGFLDEA00000127; *see also* Walgreens, *Walgreens Pharmacy and Health Care Code of Conduct and General Training*, 1-2 (June 6, 2012), WAGMDL00444056.

[1227] *See* MALLINCKRODT PHARMACEUTICALS, *Our Story,* http://www.mallinckrodt.com/about/our-story/ (last accessed Mar. 22, 2019).

[1228] *Id.*

[1229] *Id.*

[1230] *See* MALLINCKRODT PHARMACEUTICALS, *Corporate Fact Sheet*, 1 (Mar. 2018), http://www.mallinckrodt.com/globalassets/documents/corporate/corporate-fact-sheet_march-2018.pdf.

worldwide,[1231] two of Mallinckrodt's self-described strengths are being "experts in navigating the often complex terrain that comes with regulatory oversight, particularly concerning the **carefully controlled products** we manufacture," and "acquiring and handling highly regulated and complex raw materials and **controlled substances** [which] give us **unique advantages globally in the opioid** and rare disease arenas … ."[1232]

In December 2018, Mallinckrodt Pharmaceuticals announced a new plan to split into two companies.[1233] Specialty Generics would retain the Mallinckrodt name and contain the active pharmaceutical ingredient and opioid manufacturing component of the company.[1234] The other, Specialty Brands, would focus on innovative specialty pharmaceutical brands.[1235]

The manufacture and sales of controlled substances, including opioid products is a major focus of Mallinckrodt's generic business. In fact, between 1996 and 2017, Mallinckrodt was a leading manufacturer of generic opioid products, selling over $18 billion in opioid products.[1236]

The Mallinckrodt business model involved the sale of large volumes of generic finished opioid dosage units (finished tablets) to various distributors or wholesalers such a McKesson, Cardinal, and Amerisource Bergen, which in turn, supplied various retail pharmacy customers, both independent pharmacies and retail national chains (e.g., CVS and Walgreens).[1237] Mallinckrodt was also a direct distributor or wholesaler to various chain customers including CVS and Kroger Co., a retail grocery store chain with embedded pharmacies.

In 2017, Mallinckrodt entered into an agreement with the DEA to resolve the Agency's ongoing investigations and settled allegations made by the DEA that the company prior to 2012 failed to maintain and operate an effective anti-diversion program.[1238]

[1231] *Id.*

[1232] *See* MALLINCKRODT PHARMACEUTICALS, *Core Strengths*, http://mallinckrodt.com/about/core-strengths (last accessed Mar. 22, 2019).

[1233] *See* Presentation by Mallinckrodt Pharmaceuticals, Planned Spin-off of Specialty Generics Business (Dec. 6, 2018), available at http://mallinckrodt.com/investors/presentation-documents/.

[1234] *Id.* at 4.

[1235] *Id.*

[1236] *See* Jan. 30, 2019 Mallinckrodt Response to Interrogatory No. 33 & Ex. E. ["Jan. 30, 2019 MNK Rog Resp."].

[1237] Throughout this section, the terms "wholesaler" and "distributor" are used interchangeably. Their meanings are identical and connote an organization that provides opioid products from a manufacturer to a pharmacy for dispensing. In other words, a "middle man" in the classic sense of that word.

[1238] *See* Administrative Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration and Mallinckrodt plc. and Mallinckrodt LLC., 3-4 (July 10, 2017) ["Mallinckrodt AMOA"]; *see also,* John Gillies 30(b)(6) Deposition at 239:8-11 (Feb. 7, 2019) (the formal DEA investigation began in September 2011).

14.2 Executive Summary

Despite having access to voluminous data about its customers' customers (e.g., the retail pharmacies and, in certain jurisdictions, dispensing physicians), Mallinckrodt refused to take appropriate actions against its wholesalers, even when presented with evidence that those wholesalers were engaging in diversionary activities. According to the DEA, from January 2008 through September 2011, while there was an exponential increase in diversion involving oxycodone originating in Florida, which Mallinckrodt claimed they the company "still sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that would result in diversion."[1239]

Although Mallinckrodt claimed it knew nothing about the Florida situation, [1240] Mallinckrodt, through its chargeback data, had access to much of the same information as the DEA regarding these distributors and their diversionary activities.[1241] In fact, for those distributors where Mallinckrodt was the sole supplier of opioid products, which included Keysource (for all product types that Mallinckrodt supplied to Keysource)[1242] and Sunrise (for all oxycodone products)[1243], the company had access to the same information as the DEA. [1244] Rather than cut-off those distributors, which operated in an almost perpetual state of non-compliance with controlled substances requirements, the most Mallinckrodt was willing to do was cut chargeback payments to certain pharmacies, and even then, Mallinckrodt often relented under distributor pressure.[1245]

This failure to act on the data in its possession led the DEA in 2017 to accuse Mallinckrodt of not:[1246]

- Conducting adequate due diligence of its customers,

[1239] *See* AMOA at 1.

[1240] *See e.g.,* email chain between Kate Muhlenkamp-Neely and Victor Borelli re Sunrise license suspensions due to oxycodone sales to Florida (June 21, 2010), MNK-T1_0000383311; Memo from Howard Davis to Karen Harper. (Nov. 4, 2010) (warning that several Florida pharmacies are receiving oxycodone shipments through multiple Mallinckrodt distributors), MNK-T1_0000269410; Email from customer service rep Polly Jordan to Victor Borelli asking if he "heard anything about Oxycodone in Florida, and why there are so many people from Kentucky going to Florida to get their prescriptions filled?" (Mar. 4, 2009), MNK-T1_0000384265.

[1241] *See* Steven Becker Deposition at 312:11-321:12 (Dec. 19, 2018) (acknowledging that Mallinckrodt had same info as DEA re the company's sales in its chargeback system and could have evaluated same data that DEA evaluated, particularly where Mallinckrodt was the sole opioid supplier to a particular downstream customer).

[1242] *See* Email from Victor Borelli to James Rausch (Mar. 23, 2010), MNK-T1_0000312043 ("Fortunately, on all of our products at [Keysource], we are their sole supplier.")

[1243] *See* Email from Victor Borelli to Kate Muhlenkamp et al. (Nov. 12, 2008), MNK-T1_0000565624 ("We have displaced all competitors at this account, and they are relying on our supply to cover their demand.")

[1244] *Id.*

[1245] *See* "Top 20" spreadsheet for 2011 listing 20 chargeback restricted pharmacies in Florida and another 20 outside of Florida (Sept. 30, 2011), MNK-T1_0000293605. Mallinckrodt approved chargebacks for several pharmacies based on the representations and/or info provided by Cardinal, without requiring an on-site audit first. The spreadsheet contains notes of discussions with Cardinal for each of the 40 pharmacies, for e.g. for three Florida CVS pharmacies, including two in Sanford, the spreadsheet states "take CVS off the list for now, additional dialog (sic) will be conducted with CVS" … For SASB Inc. dba Okeechobee Discount Drugs, it states "ok to take off the list per agreement between Mallinckrodt & Cardinal, Cardinal will send case file."

[1246] *See* AMOA at 2.

- Detecting and reporting to the DEA orders of unusual size and frequency, as well as those orders deviating substantially from normal patterns including, but not limited to, those identified in the 2006 and 2007 Rannazzisi letters
- Using 'chargeback" information from its distributors to evaluate suspicious orders, and
- Taking effective action to prevent recurrences of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt's products by those downstream customers.

In the settlement agreement, Mallinckrodt failed to accept full responsibility for the situation, and simply conceded that "at certain times … prior to January 1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control" in 2006 and 2007.[1247]

However, the DEA's findings were mere symptoms of a far deeper problem at Mallinckrodt – a failure of culture. Mallinckrodt demonstrated repeatedly that its purported company values of being patient-centric and operating with integrity were just platitudes, and that Mallinckrodt apparently was indifferent to any negative societal impact flowing from its actions. Mallinckrodt's callousness towards the ultimate consumers of its opioid products was typified in an email exchange between Mallinckrodt's National Account Manager, Victor Borelli, and one of his distributor contacts at Keysource Medical, Steve Cochrane, after Mr. Cochrane had received an overnight shipment of 1200 bottles (e.g., 120,000 dosage units of oxycodone) from Mallinckrodt:

> Mr. Cochrane wrote: "Keep'em comin'! Flyin' out of here. It's like people are addicted to these things or something. Oh, wait, people are . . ."
>
> Mr. Borelli responded: "Just like Doritos keep eating. We'll make more."[1248]

When this email exchange was reported in *The New York Times*, a Mallinckrodt spokesman responded that it was "an outrageously callous email from an individual who has not been employed by the company for many years," and added that "[i]t is antithetical to everything that Mallinckrodt stands for and has done to combat opioid abuse and misuse."[1249] However, Mallinckrodt's current Chief Commercial Officer and previous president of the company's generics division, repeatedly refused under oath to express any opinions about the behavior, let alone condemn it as being "antithetical" to Mallinckrodt's corporate values.[1250]

[1247] *Id.* at 4.

[1248] *See* Email chain between Victor Borelli and Steve Cochrane Re Oxy 30 (Jan. 27, 2009), MNK-T1_0000559532.

[1249] *See* Associated Press, *Suit: US Drug Agency Deemed Firm 'Kingpin' in 'Drug Cartel*,' THE NEW YORK TIMES (Apr. 1, 2019), https://www.nytimes.com/aponline/2019/04/01/us/ap-us-opioid-lawsuit-tennessee html; *see also,* email from Victor Borelli to Steve Cochrane referenced in the NYT article. (Jan. 27, 2009), MNK-T1_000055953. Note that the "Doritos" conversation occurred over email not via telephone as reported in the article.

[1250] *See* Hugh O'Neill Deposition at 152:15-153:4; 155:23-158:15; 166:10-169:15; 171:10-175:19 (Mar. 13, 2019).

14.3 Impact

This systemic cultural failure, in turn, resulted in Mallinckrodt's predictable failure to implement a credible and effective anti-diversion program during the review period. Although Mallinckrodt employed a "peculiar order" approach, described as an algorithm plus due diligence on orders deemed to be "peculiar," Mallinckrodt' approach to implementing the "peculiar order" process was utterly ineffective as the table below shows.

Mallinckrodt Suspicious vs. Peculiar Orders 2003-2011

Years	Total Peculiar Orders	Total Suspicious Orders Reported
2003-2007	1,295	10-24
2008-2011	36,522	9

During the same period (2003 to 2011), Mallinckrodt shipped more than 53 million orders of opioid products.[1251] Thus, out of 53 million orders only a maximum of 33 apparently never shipped.[1252] Assuming these numbers are accurate, they are indicative of an anti-diversion program was simply *pro forma* exercise.

Mallinckrodt's lack of a credible anti-diversion program also impacted Summit and Cuyahoga Counties. For those counties, Mallinckrodt via one of its subsidiaries was the largest supplier of opioid products. Thus, between 2006-2014, Mallinckrodt shipped more opioid products – 26.7% of the total or 2,363,328,618 MMEs – than any other manufacturer.[1253]

Despite its sizeable market share, Mallinckrodt appears to have expressed zero concern that its opioid products were being diverted in Ohio. Upon receiving a news article describing the closure of a notorious pain clinic in southern Ohio along with the arrest and prosecution of its owner and a doctor at the clinic, Kevin Becker, a Mallinckrodt District Sales Manager, emailed his Regional Sales Director, Jay Meyer the following:

> "The good news he was not an Exalgo customer. Bad news is he is aligned to Heidi [a Mallinckrodt sales rep]. I did meet him. Nice guy. Oh well."[1254]

This reaction, and complete lack of concern, was not atypical.

Mallinckrodt possessed information regarding problems with diversion in Ohio, as its employees received email alerts from law enforcement regarding investigations and circulated news reports and internal emails regarding

1251 MNK-T1_0007965587 & 5588 (Mallinckrodt sales data).

1252 *Id.*

1253 See Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, ¶ 13 & Table 1 (April 15, 2019).

1254 Email from K. Becker to J. Meyer, (Dec. 28, 2011) MNK-T1_0005032855.

Ohio pill mills.[1255] Yet Mallinckrodt's former Chief Security Director testified that he was not aware of any particular problem with Ohio.[1256] In short, the opioid situation in Ohio appeared to not be a concern for Mallinckrodt despite the company possessing information demonstrating that would be extremely concerning to a prudent and responsible opioid manufacturer.

Given this, it is unsurprising that Mallinckrodt's distributors shipped opioid products to various Summit and Cuyahoga pharmacies that engaged in questionable activities involving opioids. These included Euclid Family Pharmacy and Walgreens Stores 3226, 3314, and 6574. Mallinckrodt's opioid products were supplied to all these pharmacies.[1257]

Moreover, it would be incorrect to limit Mallinckrodt's impact on Cuyahoga and Summit Counties to only those opioids that were directly shipped to these jurisdictions. Prescription opioids cross state lines, and opioids sent to jurisdictions with lax regulation, for example Florida, can easily make their way to Ohio, a fact that Mallinckrodt clearly was aware of.[1258]

Responsible compliance departments in possession of this knowledge would have expanded their focus beyond Florida to other jurisdictions in order to ascertain whether there were systemic compliance or diversion problems. There is nothing in the record indicating that Mallinckrodt ever did this for Ohio.

14.4 Company Commitment - Compliance Culture, Organization & Resources

14.4.1 Mallinckrodt's public commitment to its values of being patient-centric and demonstrating integrity does not mirror its actual practice.

Mallinckrodt has publicly stated that it is committed both to the patients who need their opioid products and to conducting their affairs with integrity, including following all laws and regulations. As expressed by Mallinckrodt's Chief Commercial Officer, Hugh O'Neill, "[w]hat we do in our business is always serious business."[1259] However, Mallinckrodt's actions paint a starkly different picture; one in which "serious business" means only the bottom line and not doing the right thing. Simply put, Mallinckrodt does not "walk

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[1255] *See, e.g.,* Email from Det. Dennis Luken to rxnews@listserve.com, [RXNews] Forged Prescription Organization, (Oct. 31, 2011) (email from law enforcement regarding organized group of doctors in Cleveland metropolitan area issuing fraudulent prescription for opioids), MNK-T1_0006029397; Email from Collidge to NADDI, [RXNews] FBI news, (Apr 20, 2012) (email regarding indictment of owner of three Ohio pain clinics), MNK-T1_000603138).

[1256] *See* William Ratliff Deposition at 33:4-14 (Dec. 19, 2018).

[1257] *See* MNK-T1_0007965587-7965588 (Mallinckrodt chargeback data).

[1258] *See* Appendix A, Figure 1. Ms. Harper gave a presentation on the "Oxy Express," the shorthand reference for the migration of pills from Florida to Ohio along the I-75 corridor. *See* Karen Harper Deposition at 91:9-92:19 (Jan. 15, 2019). John Gillies, agreed that it was "common knowledge" that people traveled to Florida to buy opioids because of the state's "lax business practices," and then transported these drugs out of the state. *See* J. Gillies 30(b)(6) Deposition at 40:8-18. In fact, Steven Becker, one the generic NAMs, was aware of the migration of pills from Florida to other states and the Oxy Express, even as he was shipping millions of pills to Florida. *See* Steven Becker Deposition, 114:1-18 (Dec. 19, 2018).

[1259] See H. O'Neill Deposition at 164:12-14.

the talk" of corporate and social responsibility, particularly as it relates to the sale and distribution of opioid products, and that tone comes from the top.

A. Code of Conduct

Although Mallinckrodt states that integrity is one of its four values and describes itself as an expert at navigating the regulatory terrain and handling controlled substances,[1260] Mallinckrodt's 42 page Guide to Business Ethics, subtitled "Integrity is Our Focus," references controlled substances only twice, and both times in the context of prohibiting employee's use of or being under the influence of controlled substances in the workplace.[1261] Therefore, while Mallinckrodt understood and was concerned over the dangers of opioid misuse in the workplace, the company failed to express a similar corresponding understanding and concern about the societal impact of misusing opioids. This is lack of regard for the societal impact is visible in the actions of Mallinckrodt's sales representatives as discussed below.

B. Sales Representative Words and Actions

The words and actions of the Mallinckrodt sales and marketing department, including statements made by individual sales employees, indicate a singular focus on the sale of opioid products, and an apparent callous disregard for societal norms or for the harm that Mallinckrodt's opioid products could cause. As noted by Ms. Harper, this callousness towards DEA's controlled substances requirements was fed by a belief the "we are 'such big players' the DEA would never suspend our license."[1262] A notion, she tried to disabuse at least Mallinckrodt's compliance employees of.

Given Mallinckrodt's dependence on its field force to support its lightly resourced Controlled Substances Compliance Group, this is troubling. Furthermore, based on the number of examples uncovered, I do not believe these are isolated actions of a few "rogue sales representatives," but rather demonstrates a profoundly flawed corporate culture.

It seems that in a misguided attempt to motivate its sales force to higher levels of performance (e.g., more sales) Mallinckrodt developed songs about its opioid products, bearing names such as "Don't Mess Around," "Give Me Moore," "Sweet Relief," "We Are Covered," "When Good Ain't Good Enough," and "When Less Can Be More.").[1263] The lyrics of Mallinckrodt's 2012 song, "Propah Dose," aptly illustrate the issue:[1264]

> You can start at the middle

[1260] *See* Discussion *infra*.

[1261] *See* Mallinckrodt, *Guide to Business Conduct*, 29 (Jan. 8, 2018), http://mallinckrodt.com/globalassets/documents/mallinckrodt_code_external_010818.pdf.

[1262] *See* Email from K. Harper to B. Ratliff, *et al.*, News on DEA Suspension of License, Amerisource-Bergen, FL, (Apr. 27, 2007) (reminding those sent the email that even big players can be suspended), MNK-T1_0000273471.

[1263] *See* announcer script for a Mallinckrodt internal radio show containing lyrics to multiple songs about Mallinckrodt opioid products (including "Don't Mess Around," "Give Me Moore," "Propah Dose," "Sweet Relief," "We Are Covered," "When Good Ain't Good Enough," and "When Less Can Be More"), MNK-T1_0002734994.

[1264] Email from M. Falcone to sales personnel announcing the availability of the Propah Dose song. (May 11, 2012), MNK-T1_0002785759.

You can start at the top
You can start with very little
But that's not where you should stop
Cause your patient needs relief, mon
. . .
So when you start at the middle
Or you start at the top
Or you start with a little
Make sure you don't stop
Cause your patient needs relief, mon[1265]

It, however, did not stop there as Mallinckrodt's sales department commissioned a video, apparently modeled on the "Dos Equis" beer commercial, which described "the most interesting physician in the world," and intoned that "[e]very time she writes a prescription, an angel gets its wings."[1266] The fact that a portion of Mallinckrodt's sales and marketing budget was devoted to these efforts is indicative of senior leadership indifference, but it also reflects a poor "tone at the top" that is not committed to compliance.

This poor compliance culture ultimately permeated the entire organization resulting in individual employees exercising poor judgment and engaging in unbecoming behavior. Perhaps the best example of how Mallinckrodt's poor compliance culture negatively impacted its employees' behavior can be seen with Victor Borelli, one of Mallinckrodt's most highly compensated National Account Managers ("NAMs").

Mr. Borelli worked for Mallinckrodt from 2005 to 2012. Before joining Mallinckrodt, Mr. Borelli was the director of coffee products for Sara Lee, and thus did not have any experience with either the pharmaceutical industry or Schedule II narcotics. In fact, Mr. Borelli was unable to identify whether certain of the products he was responsible for selling were even opioids.[1267] Nor could he recall the specifics of any compliance training.[1268]

However, as his compensation records show, Mr. Borelli was quite successful at developing relationships with his accounts.[1269] However, Mr. Borelli's callousness and lack of concern for his compliance responsibilities, as demonstrated by the "Doritos" email[1270] detailed above and other conduct, was a cause for concern among other staff members with controlled substance responsibilities. For example, Customer Service Manager Cathy Stewart warned Ms. Harper and Mr. Ratliff that the customer service representatives all said that "Borelli will tell them anything they want to hear just so he can get the sale."[1271] Mr. Borelli even characterized his job at Mallinckrodt using the phrase "ship, ship, ship."[1272] Finally, in a blatant disregard for anti-diversion

[1265] *See* Propah Dose lyrics, MNK-T1_0002734994 at 2375001.

[1266] *See* Dos Equis spoof ad, MNK-T1_0007033463.

[1267] *See* Victor Borelli Deposition at 55:19-56:19 (Nov. 29, 2018).

[1268] *Id.* at 28:9-29:23.

[1269] Excel sheet showing national account managers and bonus payments for 2007-2011, MNK-T1_0000315995.

[1270] Email chain between Victor Borelli and Steve Cochrane Re Oxy 30 (Jan. 27, 2009), MNK-T1_000559532.

[1271] *See* Email from Cathy Stewart to Bill Ratliff and Karen Harper Re Sunrise Wholesale (May 20, 2008), MNK-T1_0000290611.

[1272] *See* Email chain between Victor Borelli and Kate Muhlenkamp-Neely (Sept. 16, 2008), MNK-T1_0000563696.

compliance, Mr. Borelli emailed a distributor client asking them to check their inventories and "[i]f you are low, order more. If you are okay, order a little more. Capesce?"; and joked that the distributor should "destroy this e mail… Is that really possible? Oh Well…."[1273]

Mr. Borelli, however, was not a "rogue sales person," but a product of Mallinckrodt's poor compliance environment set from the top. Hugh O'Neill, previously the president of Mallinckrodt's generic division before becoming the current Chief Commercial Officer, when confronted with a number of instances of troubling behavior or conduct by the Mallinckrodt sales department, including Mr. Borelli's, consistently and repeatedly testified that he was unable to express any opinions about the behavior, let alone condemn it as being inconsistent with Mallinckrodt's corporate focus on "integrity" and compliance.[1274] Consequently, a member of Mallinckrodt's senior leadership claimed not to understand his company's espoused values or to be able to make a relatively "black or white" integrity call. This is an example of poor ethical leadership and company culture.

14.4.2 Mallinckrodt failed to appropriately organize and staff its anti-diversion program rendering it ineffective.

Throughout the review period, Mallinckrodt's organization and staffing of the its anti-diversion compliance team, as well as its reliance on its sales force to support the program revealed a fundamental lack of appreciation about the nature, role and importance of the anti-diversion and suspicious order monitoring programs to both Mallinckrodt and the patients it serves.

A. Organizing and Staffing the Controlled Substances Compliance Group

Prior to March 2008, there is scant evidence that Mallinckrodt had a formally designated SOM team.[1275] Mallinckrodt's anti-diversion compliance team was named first, the DEA Compliance Group ("DCG") and later, the Controlled Substances Compliance ("CSC") Group.[1276] However, Mallinckrodt's actions in organizing and staffing the CSC Group demonstrate that its public statements concerning the importance of controlled substances compliance withstanding, Mallinckrodt really did not value the program. For example, Mr. O'Neill, could not even accurately describe Karen Harper's role at the company (even though she had worked there for 40 years).[1277] Ms. Harper currently serves as Mallinckrodt's Director of Controlled Substances Compliance.[1278]

[1273] See Email from Victor Borelli to Steve Cochran, Re. things (May 20, 2008), MNK-T1_0000506535.

[1274] *See* H. O'Neill Deposition at 152:15-153:4; 155:23-158:15; 166:10-169:15; 171:10-175:19.

[1275] *See* Mallinckrodt, *Suspicious Order Monitoring Team Charter* (Apr. 7, 2011), MNK-T1_000496062 (showing team start date as 03/28/08); *see also,* J. Gillies 30(b)(6) Deposition at 101: 7-102:2 (admitting to not seeing any documentation of a SOM team or SOM program before March 2008). Mr. Gillies currently is Vice President of Global Security for Mallinckrodt.

[1276] *See* K. Harper Deposition at 23:11-17; 30:11-12.

[1277] See H. O'Neill Deposition at 153:17-154:9 (testifying that Harper "was part of the financial organization" and that he could not recall if she had any responsibilities with respect to DEA compliance and suspicious order monitoring.).

[1278] *See* K. Harper Deposition at 30:11-12.

Also, regardless of the group's name, it was small, consisting of anywhere between 3-8 individuals from 2003 to the present.[1279] As a result, for a two-year period from 2008 through 2010, a single employee – James Rausch – was tasked with reviewing all the peculiar order reports, even though this was not his full-time job.[1280] Consequently, during this period Mr. Rausch resorted to releasing peculiar orders prior to completing his due diligence on them because he didn't have enough time to complete his work.[1281]

The CSC resource limitation was further compounded by the fact that its key personnel lacked specific controlled substances experience, expertise, and training. For example, Karen Harper, who currently is the Director of Controlled Substance Compliance and whom others in Mallinckrodt considered as the definitive source for questions about the company's SOM and anti-diversion programs,[1282] had no controlled substances experience prior to joining the group, and her only training after she became a senior manager in these areas consisted primarily of attending one industry training conference per year.[1283]

B. Using the Mallinckrodt Sales Force

To supplement the limited CSC staff, Mallinckrodt relied on its sales personnel including its NAMs and Customer Service Representatives ("CSRs") to serve in active anti-diversion roles. The NAMs were considered the "eyes and ears and boots on the ground at the customer accounts," chiefly assisting in the vetting of peculiar orders while the CSRs were "veteran[s] in the business, and … in general familiar with customer's order patterns."[1284]

Despite the belief that the NAMs were trained to "be vigilant for any potential sign – red flags that could be indicative of diversion as they visited customers,"[1285] Mallinckrodt overlooked the fact that the compensation structure for the NAMs was weighted heavily to favor sales over compliance. For example, one NAM's bonuses (Victor Borelli) nearly tripled from $35,000 in 2007 to more than $100,000 in 2008-2010.[1286] The NAM compensation plan was so lucrative that Mr. Borelli exceeded his sales goals with one of his top customers, Masters Pharmacy, by more than 1,400%.[1287]

While compensation plans based on product sales are not *per se* wrong, in Mallinckrodt's case because there were no counterbalancing incentives for reporting suspicious customer orders and activity, or performing the

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[1279] *See* K. Harper Deposition at 24:23-25:2; 27:2-7.

[1280] *See* James Rausch Deposition at 133:18-134:8; 213:13-215:24 (Nov. 15, 2018).

[1281] *See* Email from James Rausch to Karen Harper (June 9, 2010), MNK-T1_0000279153; *see also,* James Rausch Deposition at 112:2-114:7 (Nov. 16, 2018) (noting that Rausch had an "agreement" with Harper that peculiar orders could be shipped prior to due diligence being completed because Mallinckrodt "didn't always have the ability to do the thorough investigation prior to the order being shipped."); *see also* Discussion *infra*.

[1282] *See* W. Ratliff Deposition at 146:8-19 (testifying that he believed Harper was "very informed and knows everything there is about DEA compliance"); *see also,* J. Rausch Deposition at 129:8-12; Ginger Collier Deposition at 214:11-24 (Jan. 8, 2019).

[1283] *See* K. Harper Deposition at 24:8-12; 49:17-50:25.

[1284] *See* K. Harper Deposition at 59:15-16; 59:23-25.

[1285] *Id.* at 59:16-19.

[1286] Excel spreadsheet showing National Account Manager bonus payments, MNK-T1_0000315995.

[1287] Excel sheet showing 2008 net sales and net sales objectives, MNK-T1_0000562520. (Borelli Deposition Ex. 4).

other anti-diversion tasks assigned to them, the company put a system in place that clearly valued sales and revenue above compliance and corporate responsibility. As a result, the NAMs were viewed as "advocates" for their distributor customers.[1288] Furthermore, Ms. Harper knew that as of November 2008, it would not be a good idea to consult with NAMS in connection with the approval of new customers, and that sales people should not be involved heavily in the identification of suspicious orders.[1289]

While the NAMs' bonuses were tied to their generic opioid sales, and those bonuses could reach six figures,[1290] Mallinckrodt apparently did not evaluate or compensate NAMs on their compliance responsibilities. Nor is there anything in the record indicating that a NAM was ever penalized for failing to stop a suspicious order. Kate Neely (formerly Muhlenkamp), the product manager for oxycodone for three years and who helped coordinate the SOM process, testified that she could not recall a single instance in which she recommended blocking a shipment of opioids to the CSC Group.[1291]

Mallinckrodt also had received warnings about its lopsided compensation system from its own staff. In 2008, Mallinckrodt's compliance personnel attended an industry conference where they learned that it was not advisable to rely so heavily on sales personnel in the SOM process.[1292] Two years later, September 2010, Ms. Harper recommended that "the actual day-to-day monitoring responsibility should be switched to a non-customer service function in that those that have responsibility to manage the orders have a conflict of interest in deciding which orders should ultimately be shipped – with ultimate right of refusal retained by Controlled Substance Compliance."[1293] However, despite these warnings, Mallinckrodt did not address the conflict situation.

14.5 Program Core – Requirements, Education, Detection & Corrections

14.5.1 Mallinckrodt's poor documentation practices were an impediment to the company's efforts to establish an effective diversion program.

Throughout the review period, Mallinckrodt's anti-diversion program, including suspicious order monitoring, was hamstrung by the company's lack of adherence to good documentation practices surrounding the development, deployment and use of written standards. Consequently, this failure undermined the overall effectiveness of the controlled substances program, and it did not comport with the compliance program standards and industry leading practices.

[1288] *See* Kate Neely Deposition at 342:5-8 (Jan. 8, 2019).

[1289] *See* K. Harper Deposition at 283:10-288:9; *see also* K. Harper Exhibit 13 (Nov. 14, 2008 email from Cathy Stewart attaching notes from the DEA Buzzeo conference, MNK-T1_000043222-226).

[1290] Excel spreadsheet showing National Account Manager bonus payments, MNK-T1_0000315995.

[1291] *See* K. Neely Deposition at 354:21-355:21.

[1292] *See* Meeting Notes from Buzzeo Conference (Oct. 27-30, 2008), MNK-T1_0000302097 (reporting the "general consensus is that sales reps are not considered a good option for on-site investigations and initial review prior to accepting new customers due to their perceived bias in getting the customer approved for sales revenue purposes.").

[1293] *See* Email from Karen Harper to Eileen Spaulding Re SOM (Sept. 24, 2010), MNK-T1_0000280260.

Prior to 2008, Mallinckrodt's anti-diversion program was marked by an absence of formal written standards. Although Karen Harper, currently Mallinckrodt's Director of Controlled Substance Compliance, noted that Mallinckrodt had a SOM program since at least 2003,[1294] it was not until 2008 that documentation in the form of a draft SOP made an appearance.[1295] She also described the program during that period as consisting of an "algorithm and some other factors."[1296]

The written standards for suspicious order monitoring and anti-diversion in effect from 2008 to 2015 are best described as chaotic. This period was marked by intensive activity that resulted in the creation of a complex and confusing set of written standards. Consequently, Mallinckrodt's anti-diversion program in this period lacked both clarity and consistency.

Ms. Harper and the CSC group began work on a suspicious order monitoring SOP sometime in April or May 2008.[1297] In October 29, 2010, a "finished" version of the SOM policy was created.[1298] While it appears to be a final version of the SOP, Ms. Harper acknowledged that as of October 31, 2010 "a final SOM procedure that outlines the criteria for identifying a suspicious order had not been finalized."[1299] Therefore, although work started in 2008, the finished SOP still was not completed and finalized at the end of October 2010, more than two years later.

According to Ms. Harper, it also was Mallinckrodt's practice that any operative drafts that CSC was "working on at the time was also the policy that [the company] would follow with respect to Mallinckrodt's suspicious order monitoring obligations."[1300] Therefore, under this process, the drafts were essentially "approved" policies or procedures, but "approved" informally only by Ms. Harper and a small group of colleagues. Thus, it appears that Mallinckrodt did not have, or Ms. Harper did not utilize, an appropriate formal document control process, making it virtually impossible to discern what the final established policy was for the SOM program at any particular point in time.

This difficulty was further compounded by that fact that beginning with the October 2010 version of C/S 3.0, Mallinckrodt ceased marking operative drafts as "drafts." Prior to this version, Ms. Harper had marked the various 2008 versions as "published drafts."[1301]

[1294] *See* K. Harper Deposition at 83:17-23 (confirming that the first reference to the existence of a SOM program at Mallinckrodt was 2003). Ms. Harper's testimony is particularly relevant because she was identified, and she confirmed, that given her long tenure with Mallinckrodt, she was most knowledgeable about the history of Mallinckrodt's anti-diversion program. *See id.* at 70:11-71:10.

[1295] *See*, *e.g.* Mallinckrodt DEA Compliance Procedure, *Controlled Substance Suspicious Order Monitoring*, Draft 2 (May 13, 2008), MNK-T1_0000268911.

[1296] *See* K. Harper Deposition at 83:24-84:3.

[1297] *See* Mallinckrodt DEA Compliance Procedure, *Controlled Substance Suspicious Order Monitoring*, Draft 2 (May 13, 2008), MNK-T1_0000268911.

[1298] *See* Mallinckrodt Global Controlled Substances Compliance Procedure, *Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program, C/S Comp. 3.0* (Oct. 29, 2010), MNK-T1_0000264260.

[1299] *See* K. Harper Deposition at 323:11.

[1300] *See* K. Harper Deposition at 435:14-20.

[1301] *See, e.g.,* Mallinckrodt DEA Compliance Procedure, *Controlled Substance Suspicious Order Monitoring*, Draft 2 (May 13, 2008), MNK-T1_0000268911; *see also* Appendix H, Figure 1 *infra* (listing the other versions of this document).

The entire approach of publishing and using operative drafts is an example of exceedingly poor document control practices and corporate governance. Drafts should never be used as "final documents," because by their very nature, they are subject to further and sometimes frequent revision. The history of Mallinckrodt's SOM procedure aptly demonstrates this. From 2008 to 2015, the *Controlled Substances Suspicious Order Monitoring* procedure and its progeny were modified fifteen times, and in the case of 2008, 2011, and 2012, there were three or more revisions per year.[1302] Nor was it until March 2011 that a document "revision history" section for the compliance written standards made its first appearance.[1303] Thus, this need for further and frequent revisions undermined the primary purpose of written standards, namely, to provide operational clarity and consistency.

Although it is not unexpected for compliance programs to have some policies and procedures that are "off-line" because they are new or being revised to reflect current operational practices, normally these periods are short-lived. When these situations occur, the organization committed to compliance will recognize the gaps or inconsistencies and create a plan to remedy them in a timely manner (e.g., a corrective action plan). However, it is outside the norms of good corporate governance, as well as a symptom of an organization's poor adherence to basic document control standards, for an organization to allow "drafts" containing gaps and inconsistencies to be used in place of final written standards and to do so unabated for periods of years, like Mallinckrodt did in this situation.

This informal approach to written standards delivered a predicable outcome; most notably confusion. For example, in 2012, while searching for Mallinckrodt's policy regarding the identification/investigation of suspicious orders, Gail Tetzlaff, Mallinckrodt's Director of Government Affairs, wrote: "I would assume this is going to be the first official Revision but when I looked in the SOP folder on the Shared Drive, I didn't see a finalized copy of our original version. What is the status of that?"[1304]

The lack of formalized written standards outlining Mallinckrodt's suspicious order monitoring program was a major shortcoming that undermined Mallinckrodt's claims about the company's efforts to meet its anti-diversion obligations. It also was not in sync with either corporate compliance program standards or industry practices.[1305] Furthermore, the need for formal written standards was something that Mallinckrodt knew or should have known it needed.[1306]

[1302] *See* Appendix H, Figure 1, *infra*.

[1303] *See* Mallinckrodt Global Controlled Substances Compliance Procedure, *Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program, C/S Comp. 2.0*, (Mar. 28, 2011), MNK-T1_0000264209; *but cf.,* Mallinckrodt Global Controlled Substances Compliance Procedure, *Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program, C/S Comp. 3.0* (Oct. 29, 2010), MNK-T1_0000264260.

[1304] Email from Gail Tetzlaff to Jennifer Buist, Re draft changes to SOM procedure (Oct. 8, 2012), MNK-T1_0008246445.

[1305] *See* Discussion *infra*.

[1306] *See generally* Discussion *infra* at Sections 4 and 5.

14.5.2 Mallinckrodt used the artifice of "peculiar orders" to avoid reporting suspicious orders to the DEA.

The concept of "peculiar orders" seems to first appear in early 2008 with Ms. Harper's initial draft of the controlled substances suspicious order monitoring procedure.[1307] As defined in that draft, a peculiar order was "[a] controlled substance order that meets an internal established criteria that will not be shipped pending further review by DEA Compliance."[1308] On the other hand, a suspicious order was defined as "[a] controlled substance Peculiar Order that has been reviewed by DEA Compliance and Security that will not be shipped and will be reported to the Drug Enforcement Administration."

Thus, within the Mallinckrodt program there were three types of orders: regular orders, peculiar orders and suspicious orders. However, according to the DEA's requirements, there are only two types of orders: regular and suspicious. Mallinckrodt, however, persisted in the belief that "a peculiar order … is not necessarily synonymous with a suspicious order" because within Mallinckrodt "certain people make the determination of whether or not the order is ultimately suspicious **sufficient to notify the DEA**."[1309]

While the term "peculiar order" is unique to Mallinckrodt, the concept is not. As discussed elsewhere in this report, every distributor at one time within the review period utilized a term of art to describe orders of unusual size, frequency or pattern that was in their opinion not a "suspicious order."[1310] The most common term being "orders of interest." Therefore, a "peculiar order" and "an order of interest" are one and the same.[1311] Furthermore, as previously discussed, neither term has any regulatory validity. Moreover, it was not appropriate for Mallinckrodt to deem a "peculiar order" as not suspicious and simply not investigate them further.[1312]

Throughout the review period, the definition of "peculiar orders" morphed over time until it finally was removed from the SOM SOP in 2012 to be replaced by the term "suspicious order."[1313] However, during the time the term was used, the various versions of "peculiar order" remained out of sync with the DEA's definitions and its expectations.

The first major change to the definition of a "peculiar order" occurred in June 2008, when Mallinckrodt removed the statement that peculiar orders "will not **be shipped** pending further review by DEA Compliance" and replaced it with language that peculiar orders "will be **placed on hold** pending review by DEA

[1307] *See* Mallinckrodt DEA Compliance, *Controlled Substance Suspicious Order Monitoring*, Revision 1 (undated), MNK-T1_0000273894. However, as Ms. Harper testified, "at different times with the enhancements of our program we [Mallinckrodt] called orders "peculiar," we called orders "unusual," and we called orders "suspicious." *See* K. Harper Deposition at 190:11-14.

[1308] *See* K. Harper Deposition at 190:11-14.

[1309] *See* K. Harper Deposition at 190:11-23; 191:2-9.

[1310] *See* Discussion *infra*.

[1311] In addition, the words "peculiar" and "suspicious" have almost the same meaning. "Peculiar" means "different to what is normal or expected," while "suspicious" means "causing one to have the idea or impression that … something is questionable …." *See* OXFORD ENGLISH DICTIONARY, "PECULIAR", https://en.oxforddictionaries.com/definition/peculiar (last visited Mar. 30, 2019); OXFORD ENGLISH DICTIONARY, "SUSPICIOUS", https://en.oxforddictionaries.com/definition/suspicious (last visited Mar. 30, 2019).

[1312] *See* Discussion *infra* Section 5.4.

[1313] *See* Covidien, *HZQS – Identification, Investigation, and Reports of Controlled Substances Suspicious Orders*, 1 (Oct. 18, 2012), MNK-T1_0007476261.

Compliance"[1314] The change in the definition is consistent with Ms. Harper's statement that "[t]here were times that we shipped an order before the [due diligence] review was complete, **but we never shipped a suspicious order.**"[1315]

The fact that Mallinckrodt allowed orders to ship without the further investigation (a.k.a. due diligence) being completed is not in conformance with DEA expectations and industry standards.[1316] As Ms. Harper conceded, if a peculiar order was released without doing further investigation or due diligence a potentially suspicious order could be shipped.[1317] Thus, Mallinckrodt knew it was shipping orders that potentially were suspicious, but did not stop shipment of them.

With the creation of a more formal SOP in October 2010, Mallinckrodt made significant changes to the definition of "peculiar order."[1318] According to this new SOP version, a peculiar order was a "[c]ontrolled substance order that meets internal established criteria of 3X the average amount of product ordered during the previous 12 months by DEA reporting class."[1319] While the new definition added the level at which an order was "flagged" as peculiar, it removed any reference that "flagged" orders were automatically placed on hold.[1320]

The October 2010 definition remained in place until the entire procedure was replaced in October 2012.[1321] With the new SOP in October 2012, the term "peculiar order" simply became a "suspicious order." In this version, Mallinckrodt defined a suspicious order as

> An order received by Mallinckrodt directly from a customer for a Schedule II – V Controlled Substance product which exceeds the internal limit set by the application of the two-tiered system of specifically created algorithms defined in this policy. Suspicious Orders will be reported to DEA upon discovery in accordance with 21 C.F.R. § 1301.74(b).[1322]

[1314] *See* Mallinckrodt DEA Compliance, *Controlled Substance Suspicious Order Monitoring*, Revision 1 (undated) (emphasis added), MNK-T1_0000273894; Mallinckrodt DEA Compliance, *Controlled Substance Suspicious Order Monitoring*, Draft #3 (June 2, 2008) (emphasis added), MNK-T1_000419993.

[1315] *See* K. Harper Deposition at 201:17-20.

[1316] *See, e.g.,* Letter from Joseph Rannazzisi to All Registrants at 2 (Dec. 7, 2007), MNK-T1 0000263492 ("Registrants who routinely report suspicious orders yet fill these orders without first ascertaining that the order will not be diverted into other than legitimate medical, scientific, or industrial channels, are failing to maintain effective controls against diversion."); *see also* HDMA *Position Statement and Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances* (2008), WAGMDL00673706-673722.

[1317] *See* K. Harper Deposition at 203:1-17.

[1318] *See* Mallinckrodt Global Controlled Substances Compliance Procedure, *Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program, C/S Comp. 3.0,* 2 (Oct. 29, 2010), MNK-T1_0000264260; *see also* Appendix H, Figure 2 *infra.*

[1319] *See id.* at MNK-T1-0000264260.

[1320] *Id.*

[1321] *See* Covidien, *HZQS – Identification, Investigation, and Reports of Controlled Substances Suspicious Orders*, 1 (Oct. 18, 2012), MNK-T1_0007476261.

[1322] *Id.* at 1.

Therefore, 2012 is the first time that Mallinckrodt's definition of suspicious orders began to track with the DEA's definition. However, nowhere in the procedure was there a clear definition that a suspicious order is an order of unusual size, frequency or pattern, but instead it is couched in terms of exceeding an established threshold. Furthermore, there was no precise designation of when a suspicious order is "discovered" (e.g., is it when the algorithm flags the order or when the SOM Leadership team completes its review).[1323] The new procedure did reinstate language about automatically generating a "ship-hold" on orders until a final, written determination was made.[1324] This approach to suspicious orders carried over into the post-2013 era as seen in the 2015 version.[1325]

14.5.3 The Mallinckrodt suspicious order program was flawed both in its design and implementation rendering it ineffective to detect suspicious orders.

Using the concept of "peculiar orders" Mallinckrodt developed a two-tier approach to suspicious order monitoring. The first tier consisted of an automated algorithm to "flag" orders as peculiar. The second tier involved conducting due diligence on the orders identified as peculiar to determine whether they were truly "suspicious" and thus reportable to the DEA.

A. The Peculiar Order Algorithm and Due Diligence

It appears that by 2003 Mallinckrodt employed some sort of automated algorithm to identify suspicious orders.[1326] Although the algorithm was the primary method for identifying peculiar orders, in some cases both the National Account Managers and Customer Service Representatives could identify an order as "peculiar" independent of the algorithm.[1327]

From March 2008 onwards with the formation of the SOM Team, Mallinckrodt worked to refine and document its algorithmic model.[1328] That work continued through 2009 and stretched into 2010.[1329] From its inception, as recounted by James Rausch, Mallinckrodt's Customer Service Manager for Finished Goods, the peculiar order

[1323] *Id.* at 2, § 6.4.1 and 3, § 6.4.8.

[1324] *Id.* at 2, § 6.3.1.

[1325] *See generally,* Mallinckrodt Pharmaceuticals, *HZQS – Identification, Investigation, and Reports of Controlled Substances Suspicious Orders*, (Aug. 17, 2015), MNK-T1_0000511246.

[1326] *See* K. Harper Deposition at 83:24-84:3 (The Mallinckrodt SOM program at that time employed an "algorithm and some other factors."). However, since there was no dedicated SOM team until March 2008 there is little documentation to support Mallinckrodt's practices in the pre-2008 timeframe. *See* Mallinckrodt, *Suspicious Order Monitoring Team Charter*, (Apr. 7, 2011) (Showing team start date as 03/28/08), MNK-T1_000496062; *see also* J. Gillies 30(b)(6) Deposition at 101:7-102:2 (admitting to not seeing any documentation of a SOM team or SOM program before March 2008).

[1327] *See* K. Harper Deposition at 196:16-197:10; 197:15-22.

[1328] *See, e.g.,* Mallinckrodt, *Suspicious Order Monitoring Program Dosage Products Shipments from Hobart – Activities 10/2008 through 8/10*, 1 (undated), MNK-T1_0000477889 ("SOM Team Activity Log").

[1329] *Id.* at 4 (showing continued interactions between the SOM Team and IT concerning the algorithm).

algorithm was a simple size algorithm that was baked into Mallinckrodt's JD Edwards order entry system[1330] and flagged orders in excess of twice the rolling monthly average order.[1331] Orders identified as "peculiar" were compiled into the "Peculiar Order Daily Reports," which were "algorithm reports that show[ed] any orders regarding the unusual size, pattern, et cetera."[1332]

Orders listed in the Daily Reports were then "reviewed by a customer service representative."[1333] However, the review of orders by Customer Service was limited only to those orders on the daily report.[1334] Therefore, orders that did <u>not</u> trigger the "peculiar order" threshold were <u>not</u> subjected to further scrutiny, even if there may have been other reasons for the order to be deemed suspicious, notwithstanding its relative size.[1335] Thus, it was possible for suspicious orders not flagged by the algorithm to escape detection and be shipped to the customer.[1336]

Even using the "Peculiar Order Daily Report" and review by a customer service representative, Mallinckrodt could, and at times did, still ship orders on the report. As Mr. Rausch explained to Ms. Harper "[a]s we discussed I do not hold **any** orders while I do my research due to time constraints … it takes time to get information back from Marketing and sales, sometimes all day."[1337] He also noted that "[s]ince I don't hold the orders up during my due diligence it's possible that the order could ship. I thought we discussed this and alerting the DEA about a suspicious order/customer for further investigation would be our process going forward."[1338]

Mallinckrodt shipped peculiar orders prior to completing any further due diligence, because it "didn't always have the ability to do the thorough investigation prior to the order being shipped" due to time constraints.[1339] As Ms. Harper characterized it, "[t]here were times that we [Mallinckrodt] shipped an order before the [due diligence] review was complete, **but we never shipped a suspicious order.**"[1340] During his testimony, Mr. Rausch stated that the company felt comfortable with this practice "because that order was going to a distributor

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[1330] *See* J. Rausch Deposition at 194:3-10 (the algorithm was part of the computer code for the order entry system, known as JD Edwards or JDE, an Enterprise Resource Planning ("ERP") software platform).

[1331] *See* J. Rausch Deposition at 44:12-45:16.

[1332] *See* J. Gillies 30(b)(6) Deposition at 83:18-22.

[1333] *See* Mallinckrodt DEA Compliance Procedure, *Controlled Substance Suspicious Order Monitoring*, Draft #2, 2 (May 13, 2008), MNK-T1_0000268911.

[1334] *See* J. Gillies 30(b)(6) Deposition at 92:7-18 (confirming that Customer Service only reviewed peculiar orders and not every customer order).

[1335] *See* J. Rausch Deposition at 194:3-23 (confirming that if an order was not flagged by Mallinckrodt's algorithm, it was not examined; and acknowledging that if there were gaps or faults in the algorithm, it was possible for problematic orders to get through.)

[1336] *Id.*

[1337] Email from James Rausch to Karen Harper and George Saffold Re Suspicious Order Monitoring Program (June 9, 2010) (emphasis added), MNK-T1_0000279153.

[1338] *Id.*

[1339] *See* J. Rausch Deposition at 112:14-24.

[1340] *See* K. Harper Deposition at 201:17-20 (emphasis added); *see also* Email from K. Harper to J. Rausch and G. Saffold Re Suspicious Order Monitoring Program (June 9, 2010) ("I merely wanted to confirm that we have not shipped any suspicious orders (even if we do the investigation after the shipment)."), MNK-T1_0000279153.

who also had a program in place for suspicious orders, so we knew **we could get the product back or stop it if need be**."[1341]

How frequently shipments went out without completing due diligence is a matter of some debate. Cathy Stewart, a Customer Service Manager for Mallinckrodt, recounted that she could not recall a single peculiar order being held.[1342] Regardless of how frequently this situation occurred, it was clear that if a peculiar order was released without doing further investigation or due diligence, a potentially suspicious order could be shipped.[1343]

Even when an "investigation" of a peculiar order was undertaken by the Customer Service and the CSC group, it was at best rudimentary, and primarily based upon information provided by the NAMs, who had a conflict of interest. The record indicates that the NAMs simply collected information from their distributor customers and then passed it onto the compliance group, which then simply relied on that information.[1344] In fact, Mr. Borelli simply forwarded inquiries from his compliance department to his wholesale customer, though he claimed to also have followed up with a phone call. [1345]

As a result, the justifications used to push orders through generally consisted of two- or three-line emails citing various "marketing rationales." For example, there was: (a) the fact that a customer was an "established customer"[1346]; (b) that the customer had a new account that was ordering a lot of oxycodone[1347]; (c) that the customer had expanded its customer base to other states[1348]; (d) that the NAM wanted to keep the "momentum rolling" with a customer[1349]; (e) that the customer needed to increase its order volume in order to comply with contractual provisions requiring it to order more opioids to secure favorable pricing[1350]; (f) that the customer was dramatically increasing its orders to meet customer demand[1351]; and (g) assuming that a customer's inability to obtain opioids from another source justified filling an order many times above historical levels.[1352]

[1341] *See* J. Rausch Deposition at 113:23-114:7 (emphasis added).

[1342] *See* Cathy Stewart Deposition, 111:8-12 (Dec. 11, 2018).

[1343] *See* K. Harper Deposition at 203:1-17.

[1344] S. Becker Deposition at 281:13-21; 287:21-13.

[1345] V. Borelli Deposition at 280:2-281:2.

[1346] Email from Bill Ratliff to James Rausch *et al*. Re Propoxyphene Napsylate orders for Sovereign (Sept 3, 2008), MNK-T1_0000290520.

[1347] Email from Steven Becker to Karen Harper *et al*. Re Old Bridge account (Oct. 28, 2008), MNK-T1_0000448888.

[1348] Email from Victor Borelli to Kate Muhlenkamp (Nov. 14, 2008), MNK-T1_0000290502 (noting that new Sunrise Wholesale sales manager is "extremely tied into the Florida market").

[1349] Email from Victor Borelli to James Rausch Re Peculiar order report (Mar. 23, 2010), MNK-T1_0000297371.

[1350] Emails from Steven Becker to Penny Myers and James Rausch Re HD Smith (May 5, 2010), MNK-T1_0000298906.

[1351] Email from Victor Borelli to Brenda Rehkop *et al.* (Jun. 23, 2010), MNK-T1_0000560555 (explaining Oxy's historical movement through wholesaler and distributor accounts).

[1352] Email from Bill Ratliff to Kate Muhlenkamp *et al.* Re Oxycodone orders (Jun. 4, 2008), MNK-T1_0000562682.

Moreover, if the NAM justified a peculiar order based simply on a distributor's increased sales or market share, the CSC group approved the order on that basis. As Ms. Harper stated in a July 2010 email, "[i]ncreased market share . . . is a satisfactory explanation from the Suspicious Order Monitoring perspective."[1353]

Overall, Mallinckrodt's undue reliance on the peculiar order algorithm, and its shipment of orders flagged by that algorithm with little or no further due diligence is problematic in two significant respects. First, as the DEA counselled, algorithms are not perfect and "[r]egistrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders."[1354] This was known and acknowledged by both Mr. Rausch and Ms. Harper.[1355] It also was something that the customer service department warned CSC about in 2009 noting that the algorithm potentially allowed customers to evade the system by gradually increasing their order volume to avoid triggering the threshold.[1356]

Second, there was a DEA expectation that if an order is flagged as suspicious, the company should not ship it until an appropriate investigation is undertaken.[1357] In April 2008, Paul "Pete" Kleissie, DEA Diversion Group Supervisor, inquired about why Mallinckrodt was filling peculiar (i.e., suspicious) orders telling Mallinckrodt succinctly: "'If you think it is suspicious, don't fill it.'"[1358] Mallinckrodt, however, misconstrued Mr. Kleissie's statement as "if you're going to ship it, it's not suspicious."[1359]

Therefore, even though the regulatory requirements and expectations surrounding controlled substances compliance were well established by 2008, Mallinckrodt selectively interpreted those requirements and expectations in such a manner so not to impact their continued distribution of opioid products, although doing so rendered its anti-diversion program ineffective.

In addition to the issues noted above, from the outset, the peculiar order algorithm was highlighting too many orders as peculiar. In April 2009, Ms. Harper wrote, "[w]e have working algorithms, and J. Rausch has been reviewing peculiar orders for several weeks. I have a meeting with Jim tomorrow because **the review is taking several hours a day**, yet still results in him making **a judgment call that he is not comfortable with**."[1360] Later in July 2009, the SOM Team Activity Log noted that the "[p]eculiar order report being generated based upon algorithm settings is 49 pages long."[1361]

[1353] Email from Karen Harper to James Rausch *et al.* Re Oxycodone HCL (Jul. 13, 2010), MNK-T1_0000265505.

[1354] *See* Letter from DEA Deputy Asst. Administrator Joseph Rannazzisi to Mallinckrodt, (Dec. 27, 2007), MNK-T1_0007146632.

[1355] *See* J. Rausch Deposition at 194:3-23; K. Harper Deposition at 203:1-17.

[1356] *See* SOM Team Activity Log at 3, MNK-T1_0000477889 (quoting an email from Cathy Stewart in July 2009 "[w]e need to investigate and make sure they're not just gradually increasing their order quantities to not get caught by the 2X formula threshold.").

[1357] *See* J. Rannazzisi Letter to All Registrants at 2 (Jul. 27, 2007), MNK-T1_0007146632 ("[R]egistrants that routinely report suspicious orders yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion.")

[1358] *See* Email from B. Ratliff to J. Rausch (Apr. 1, 2008) (K. Harper was copied on that email and Mr. Kleissie was quoted in it.), MNK-T1_0000268860.

[1359] *See* K. Harper Deposition at 258:14-259:3.

[1360] *See* Email from Karen Harper to Eileen Spaulding Re Suspicious order monitoring (Apr. 29, 2010) (emphasis added), MNK-T1_0000279142.

[1361] *See* SOM Team Activity Log at 4, MNK-T1_0000477889.

As a result of this ongoing "administrative burden" from having too many orders to review,[1362] Mallinckrodt resorted to simply turning off a portion of the algorithm sometime in 2009 through April 2010.[1363] Without a fully functioning algorithm, Mallinckrodt had fewer orders to review, but this reduced burden came at the cost of increasing the risk that suspicious orders could slip through. In addition, from 2008 to 2009, Mallinckrodt simply disabled its algorithm altogether, thereby limiting the customer services representatives review to determine if an order was peculiar to:

- Verifying that the account is in good standing by referencing the "Do Not Ship List."
- Assuring that the order is valid.
- Checking the customer DEA registration status
- Verifying customer has provided a DEA 222 form.[1364]

If there were any exceptions in the information, the order was deemed "peculiar."[1365] However, Mallinckrodt knew that confirmation of the customer's current DEA registration and status and receipt of a DEA 222 form alone were not appropriate in determining whether an order is suspicious.[1366]

At the end of April 2010, Mallinckrodt resumed using the full peculiar order algorithm, but had increased the historical average sales from 2X to 3X to reduce the number of peculiar orders identified.[1367] Mallinckrodt implemented this change despite recognizing the already heightened risk that customers could evade detection of their suspicious orders by gradually increasing their order volume to avoid triggering the threshold.[1368] However, rather than increasing the CSC group's resources and possibly disrupting the flow of sales and revenue, Mallinckrodt deemed the risk acceptable and memorialized the change in the October 2010 version of the SOM procedure.[1369]

[1362] *See* K. Harper Deposition at 321:20-25.

[1363] *See* SOM Team Activity Log at 4, MNK-T1_0000477889. ("30 Day Cumulative Algorithm is turned off because that specific trigger was not spelled out in HDMA guidance and is inflating the peculiar order count").

[1364] *See* Mallinckrodt DEA Compliance Procedure, *Identification and Review of Peculiar Orders, Controlled Substance Suspicious Order Monitoring Program*, Draft 4 (Jul. 15, 2008), MNK-T10000263965.

[1365] *Id.*

[1366] Email from Karen Harper to John Adams *et al.* Re Suspicious Order Monitoring Training Notes from Bulk Narcotic Sales Meeting Presentation (Jun. 6, 2008), MNK-T1_0000419956; *see also* J. Rausch Deposition at 139:14-140:9 (other than verification of the 222 forms Mallinckrodt did not have a suspicious order program in place between fall of 2008 and 2009); William Ratliff Deposition, 242:2-9 (Dec. 19, 2018) (agreeing that it would not be proper to just rely solely on registration status and the 222 form in determining whether or not to ship an order).

[1367] *See* K. Harper Deposition 321:11-25 (justifying moving from a 2x to 3x formula because the peculiar order report was "too lengthy" and was creating too much of an "administrative burden").

[1368] *See* SOM Team Activity Log, MNK-T1_0000477889 (providing a timeline of the SOM program and noting concern with customers gradually increasing their orders).

[1369] *See* Global Controlled Substance Compliance Procedure, *Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program,* C/S Comp. 3.0 (Oct. 29, 2010), MNK-T1_0000264260.

On November 1, 2012, Mallinckrodt changed its procedures for identifying suspicious orders again. Mallinckrodt's new system created separate controls for Oxy 15 and 30 sales to large distributors ("Tier 1") and changed to [redacted] its "standard" algorithm for other sales ("Tier 2"):

> Tier 1: A monthly limit set annually for large volume wholesalers' or distributors' orders of Oxycodone 15 mg and 30mg SKUs. These products have been identified by DEA as particularly subject to diversion and abuse.
>
> Tier 2: A standard algorithm with respect to volume which sets a [redacted][1370]

B. Howard Davis' Concerns

In late 2010, Mallinckrodt retained a former DEA employee, Howard Davis, to specifically evaluate its SOM program.[1371] As part of his work assisting Mallinckrodt in evaluating its SOM program, Mr. Davis authored a memorandum in November 2010 that was critical of Mallinckrodt's then current SOM approach.[1372]

Mr. Davis highlighted his concerns about Mallinckrodt's algorithm, and his feeling that when Mallinckrodt applied the formula in certain situations, it "would be unnecessarily exposing itself to potential liability."[1373] Specifically, Mr. Davis was concerned that Mallinckrodt was relying too heavily on the numeric formula while not investing a corresponding amount of effort into investigating orders exceeding the threshold levels (a.k.a. order due diligence).[1374] As Mr. Davis outlined for Mallinckrodt:

> Numeric formulas do not identify circumstances that might be indicative of diversion such as: ordering larger quantities of a limited variety regularly that would otherwise not be viewed as suspicious (like ordering controlled substances with few, if any, other drugs or products whether controlled or non-controlled); ordering highly abused controlled substances in limited quantities disproportionate to other products; or even ordering the same controlled substances from multiple suppliers.[1375]

To further support his conclusion, Mr. Davis highlighted previous DEA Guidance concerning a manufacturer's "Know Your Customer" obligations as well as recent enforcement actions.[1376]

[1370] *See* Covidien Procedure, *HZQS – Identification, Investigation, and Reports of Controlled Substances Suspicious Orders*, 1 (Nov. 1, 2012), MNK-T1_0005620500.

[1371] *See* Consulting Agreement between Mallinckrodt and Howard Davis (Oct. 18, 2010), MNK-T1_0000427406.

[1372] Memorandum from Howard Davis to Karen Harper, *Suspicious Order Monitoring Program No. C/S Comp 3.0*, (Nov. 2, 2010), MNK-T1_0000269399.

[1373] *Id.* at 1.

[1374] *See id.* ("DEA has determined that algorithms and/or arithmetic formulas to define whether an order is suspicious may be failing to detect suspicious orders").

[1375] *Id.* at 2.

[1376] *See id.* at 1; *see generally* DEA Guidance discussion *infra* at Section 5.3.

In order to remedy the observed deficiencies, Mr. Davis recommended that Mallinckrodt immediately revise its Global Controlled Substance Procedure entitled "Identification and Review of Peculiar Orders" to include criteria "such that a more vigilant determination can be made whether the order is suspicious and/or excessive prior to filling any order, in concert with numeric formulas already in place as the Company deems appropriate."[1377] By doing so, Mallinckrodt would evaluate the "totality of the circumstances when evaluating an order prior to it being filled, just as the DEA will do in determining if the registrant is operating within the public interest …."[1378]

Mr. Davis recommended adding the following customer inquiries to Mallinckrodt's program:

- What percentage of business do controlled substances constitute?
- Is the customer complying with other federal, State, local requirements/laws?
- Is the customer soliciting and/or supplying customers via the Internet unlawfully?
- Does the customer have a business relationship with a physician or other business partner who authorizes prescriptions over the Internet?
- Are prescribing practitioners licenses in the State where the controlled substances are being shipped?
- Are shipments made where the majority of the ultimate customers are serviced from the same practitioner who routinely authorizes "cocktail" prescriptions, i.e., drug combinations that compound or have an antagonistic effect?
- Are controlled substances sold to retail outlets that further dispense them without a prescription?
- Does the customer sell controlled substances for market prices of well above state-of-the-art pricing modules?
- Are sells [sic] made to customers, or their customers, on a cash only basis or are insurance plans accepted? [1379]

He also went further and provided Mallinckrodt with a roadmap in the form of a draft SOP.[1380]

After receiving the report, Ms. Harper directed Mr. Davis to "revise the QSP Order Monitoring document, incorporate recent program enhancements with recent activities."[1381] Mr. Davis complied and provided some modifications to the procedure that including adding to the "Overview" section the following statements that the procedure was used to:

[1377] *Id.* at 2.

[1378] *Id.*

[1379] *Id.*

[1380] *See Standard Operating Procedure, Due diligence procedures and monitoring of controlled substances sales*, (undated), MNK-Ti_0000269401.

[1381] *See* Email from K. Harper to H. Davis Re Revision of QSP Order Monitoring Attached, (Nov. 18, 2010), MNK-T1_0000264240 (referring to the Global Controlled Substances Compliance Procedure entitled "Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program," C/S Comp. 3.0, MNK-T1_0000264260).

- Insure (sic) that the chargeback system exists to reimburse wholesalers for discounted pricing to collective buying groups so it does not otherwise flag an order as suspicious
- Insure (sic) that the customer ultimately receiving controlled substances through a buying group has supplied documentation validating any order placed prior to shipment.[1382]

Within approximately two weeks of receiving Howard Davis' critical memo, it appears Karen Harper and Mallinckrodt were preparing to fire Mr. Davis. In an internal email dated November 17, 2010, Ms. Harper characterized Mr. Davis's termination as "Mallinckrodt 'firing' Howard 'quitting'" and she drafted talking points to characterize his departure in terms such as "we are going in a different direction with the program" and "have to do more with less resources."[1383] In January 2011, Ms. Harper told Mr. Davis that Mallinckrodt would not need his "services in the near future," and she disconnected his laptop and telephone.[1384]

In the weeks and months after Mr. Davis presented his memorandum to Mallinckrodt, the CSC group issued a multitude of new procedures in various drafts and versions, including:

- C/S Comp. 2.0 - New Customer Account Set-up, Existing Account & Ongoing Review[1385]
- C/S Comp. 4.0 - Customer Audit Program[1386]
- C/S Comp. 5.0 - Identification & Review of Suspicious Customer Accts.[1387]

14.5.4 Mallinckrodt failed to effectively know their customers' customer despite having enough information to create a robust system to do so.

Mallinckrodt understood the importance of knowing your customer's customer as far back as 2008 and were informed that the DEA expected this of Mallinckrodt in the summer of 2010. DEA, during a July inspection to the Hobart facility, requested an "impromptu meeting" with Mallinckrodt and Ms. Harper.[1388] At the meeting, the DEA Diversion Group Supervisor informed Ms. Harper that the DEA was pursuing a "'new direction

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[1382] *See* Global Controlled Substances Compliance Procedure, *Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program,* C/S Comp. 3.0 (undated with handwritten notation "Howard Davis Revision"), MNK-T1_0000269954 ["Davis Revision to C/S Comp. 3.0"]

[1383] Internal notes prepared by Karen Harper (MNK-T1_0000280821).

[1384] *See* Email from K. Harper to D. Hunter, Consultant (Howard Davis) Desk Phone and Laptop on Z-4, (Jan. 18, 2011), MNK-T1_0000281479. However, as Mallinckrodt was firing Mr. Davis, the market for Oxycodone 15 and 30 mg appeared to be at or near its peak. *See Oxy Florida Sales*, MNK-T1_0000289708 (Sept. 14, 2010); *See* Presentation by Mallinckrodt, *Generics Demand Review* Presentation, slide 34 (Jul. 7, 2010), MNK-T1_0007097723.

[1385] *See* Global Controlled Substances Compliance Procedure, *New Customer Account Set-up and Existing Customer Account Ongoing Review*, (Jan. 4, 2011), MNK-T1_0000264279; MNK-T1_0000264209 (Mar. 28, 2011), MNK-T1_0000259157 (Aug. 8, 2011).

[1386] *See* Global Controlled Substance Compliance Procedure, *Customer Audit Program*, (Jan. 4, 2011), MNK-T1_0000264214; MNK-T1_0000264205 (Mar. 28, 2011), MNK-T1_0000259162 (Aug. 8, 2011).

[1387] *See* Covidien, *Identification and Review of Suspicious Customer Accounts,* (Aug. 8, 2011); MNK-T1_0000259153.

[1388] *See* Email from K. Harper to T. Berry, Re DEA Dialogue 07/20/10 – Suspicious Order Monitoring and Harvard Drug License Suspension, (Jul. 21, 2010), MNK-T1_000269747.

initiative' whereby enforcement action will be aimed at all entities within the supply chain, including manufacturing registrants."[1389]

Therefore, as Ms. Harper learned from the DEA "[t]he expectation is becoming that suppliers have not only an obligation to know their customers but an additional responsibility to know their customers." According to Ms. Harper, this was particularly important to the DEA because actions taken against Florida pain clinics for oxycodone diversion were causing those clinics to relocate to Georgia, Ohio, and Texas.[1390]

A. The SOM Customer Checklist (a.k.a. SOM Customer Questionnaire)

Another important control that Mallinckrodt employed for anti-diversion purposes was the Suspicious Order Monitoring Customer Checklist. This document was provided to new accounts when they were first set-up and annually to all existing customers.[1391] This checklist constituted one of Mallinckrodt's primary sources of information about its customers and was deployed in July 2009.[1392]

Steven Becker, one of the NAMs, was asked to help put together the questionnaire.[1393] The intent behind it was to provide it to Mallinckrodt's customers and confirm that they were looking at various factors that would help them "identify suspicious orders."[1394] The factors in the questionnaire Becker helped prepare – for example the ordering of excessive quantities of controlled substances and the ordering of controlled substances in quantities disproportionate to non-controlled medications – were based on the Rannazzisi letters, and by Becker's own admission applied to all of his customers.[1395]

After the July 2010 "impromptu meeting," Ms. Harper and CSC Group changed the SOM Customer Questionnaire to remove the question on whether "our customers monitor their customers."[1396] In an August 2010 email communicating the change, Ms. Harper explained that the SOM Team's decision was based on the fact that "there is no actual regulatory obligation to monitor customers' customer."[1397] In an ironic juxtaposition of roles, Kate Muhlenkamp, Covidien Product Manager, advocated for retaining the question noting that "[f]rom our perspective (Sales & Marketing), we think it would be a very good idea to require it

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1389 *Id.*

1390 *Id.*

1391 *See* Global Controlled Substance Compliance Procedure, *New Customer Account Set-up and Existing Customer Account Ongoing Review*, C/S Comp. 2.0, 2 (Jan 4, 2011), MNK-T1_0000264280.

1392 *See* SOM Team Activity Log at 2, MKN-T1_0000477889 ("072009 CDIG begins sending out SOM customer questionnaires.").

1393 S. Becker Deposition at 349:21-24.

1394 S. Becker Deposition at 351:4-11.

1395 S. Becker Deposition at 369:9-370:15, 371:14-372:18.

1396 *See* Email from K. Harper to G. Collier and K. Muhlenkamp Re Distributors Protocol for Vetting Customers (Aug. 26, 2010), MNK-T1_0000368388.

1397 *Id.*

despite it not being a regulatory obligation."[1398] However, Ms. Harper did not agree nor did she see the removal of the question as a problem although it effectively diluted the effectiveness of the questionnaire.[1399]

Ms. Harper removed this question despite the fact she was aware that DEA expected Mallinckrodt to undertake KYCC.[1400] Given the fact both the DEA and Mallinckrodt's own sales and marketing team thought knowing whether Mallinckrodt's customers monitored their customers was important, removing the question from the SOM Customer Checklist was the act of an imprudent company which did not view controlled substances compliance as important. Furthermore, it is troubling when the appointed gatekeepers (compliance) endeavor to dilute the very controls they are charged with protecting.

However, in the end, removal of this question potentially had little impact because Mallinckrodt's Customer Data Integrity Group ("CDIG"), which had responsibility for ensuring that Mallinckrodt's customers completed the questionnaire, simply allowed Customer Service to renew accounts even though they failed to complete the form. This prompted Ms. Harper in February 2011 to write Eileen Spaulding, a Compliance Analyst in the Mallinckrodt Dosage Group:

> I think I discovered a disconnect in the system. We have significant gaps in that, although CDIG send out the Annual Update SOM Customer Checklist when the system indicates customer account DEA registration is nearing renewal time, THEY DO NOTHING IF THE SOM CUSTOMER CHECKLIST IS NOT EVER RETURNED BY THE CUSTOMER, CDIG primary concern is the license renewal. … sometimes CSR[s] [Customer Service Representatives] update the license renewal info … and then CDIG NEVER SENDS AN ANNUAL CHECKLIST. [1401]

Mallinckrodt was aware that DEA expected all registrants to know their customers and in the case of manufacturers that companies were expected to know their customers' customer. This was a fundamental part of a reasonable and effective SOM program. Both Ms. Harper and Mr. Ratliff, former Chief Security Officer, acknowledged that knowing your customer's customer is a component of an effective SOM program,[1402] and Mr. Ratliff conceded that as early as June 2008 Mallinckrodt understood the importance of knowing your customers' customers.[1403] Yet despite this knowledge and the explicit feedback to the company by the DEA, Mallinckrodt failed to incorporate a credible KYCC framework into its anti-diversion program.

[1398] *See* Email from K. Muhlenkamp to K. Harper and G. Collier Re Distributors Protocol for Vetting Customers (Aug. 26, 2010), MNK-T1_0000368390.

[1399] *See* K. Harper Deposition at 344:22-345:6 (stating that removing the question "was not a detriment to the program").

[1400] *Id.* at 345:7-20.

[1401] Email from K. Harper to E. Spaulding Re DEA Registration verification, (Feb. 11, 2011), MNK-T1_0000372333 (emphasis in original).

[1402] *See* K. Harper Deposition at 79:10-80:5; W. Ratliff Deposition at 107:4-16.

[1403] *See* W. Ratliff Deposition at 104:14-106:2.

B. Chargeback Data

Chargebacks are a common pharmaceutical tool used by manufacturers to make distributors "whole" when they sell pharmaceuticals to pharmacies at prices below what the distributor paid to the manufacturer.[1404] Since chargebacks represent a loss to the pharmaceutical manufacturer, the industry expends significant resources on its systems and processes to minimize chargebacks and ensure the legitimacy of chargeback claims.[1405] This was true in Mallinckrodt's situation.

In order to interrogate the legitimacy of a chargeback claim, the manufacturer requires specific data on the transaction including the actual customers and the discounted levels at which products were sold to pharmacy customers by the company's distributors to their customers. As a result, since at least 1998, Mallinckrodt maintained an extensive chargeback database that traced with great granularity sales to the customers of Mallinckrodt's distributors.[1406]

According to Ms. Harper:

> Mallinckrodt sells controlled substances to wholesalers at a standard price. Some pharmacies negotiate a discounted price. When the wholesaler honors the discounted price to the pharmacy, they then submit a charge back request retroactively to Mallinckrodt so that they can be made financially whole for the difference in price. In doing so the **wholesaler tells Mallinckrodt exactly which pharmacy to which the drugs were sold, what the DEA registration number is, the pharmacy address, the quantity, and which drugs they have sold to that pharmacy**.[1407]

With access to the chargeback data, Mallinckrodt personnel, including the NAMs, who functioned as the "boots on the ground" for the compliance department, had the downstream visibility that the chargeback data provided to both direct and indirect customers.[1408] Mallinckrodt had chargeback data for virtually all transactions with its wholesale distributor customers.[1409] This data essentially gave Mallinckrodt visibility into entire supply chain for its products, from manufacturer to distributor to pharmacies and other end dispensers.

[1404] *See* Tyler Lacoma, *What is a Pharmaceutical Chargeback?,* BIZFLUENT (updated Nov. 21, 2018), https://bizfluent.com/info-8783464-pharmaceutical-chargeback.html.

[1405] *Id.*

[1406] *See* MNK-T1_0007965587-7965588 (chargeback data for 1998-2018 produced by Mallinckrodt in this litigation).

[1407] *See* Deposition of Karen Harper at 11:15-25 (Nov. 7, 2013), Harper Exhibit 9; Apothecary Corporation d/b/a Island Drug v. City of Marco Island, Florida, Case No. 2:10CV-392FtM-36-DNF (M.D. Fla. 2013).) K. Harper Deposition at 227:13-18. In correspondence with the DEA, Ms. Harper described how Mallinckrodt obtains chargeback data and that "distributors must provide Mallinckrodt with specific detailed information indicating how much product was sold to each end user pharmacy."; *see also,* Letter from K. Harper Letter to P. Kleissle (Nov. 1, 2010), MNK-T1_0000280607.

[1408] *See, e.g.,* V. Borelli Deposition at 130:5-136:24; S. Becker Deposition at 158:13-18, 161:24-163:1.

[1409] *See* K. Harper Deposition at 229:15-18. Ms. Harper informed the DEA that Mallinckrodt "assumes most transactions would result in a chargeback request" by a distributor. *See* Email from K. Harper to K. Hamilton Re Explanation of Mallinckrodt Chargeback System (Nov. 2, 2010), MNK-T1_0000387492. For example, 96% of all Oxy 15 orders and 98% of all Oxy 30 orders were subject to chargeback requests, and hence would be in the chargeback database. J. Gillies (30)(b)(6) Deposition at 271:3-274:2.

While Mallinckrodt was aware of the power of chargeback data in 2007, it was not until the 2009-2010 timeframe that the CSC Group became interested in using the data.[1410] Even then, Ms. Harper was slow to utilize chargeback data – in fact, despite acknowledging that it would not be complicated to pull the chargeback data and receive training for how to utilize it, it took Ms. Harper at least four months between when she first asked about the chargeback data in late 2009 and when she actually purportedly took action on it later in 2010.[1411]

In another ironic juxtaposition of roles, Ginger Collier, the Director of Marketing for generics, related that she directed Kate Muhlenkamp Neely, the product manager for oxycodone, to analyze chargeback data relating to the sale of opioid products to doctors in Florida.[1412] The data revealed that many pharmacies and pain clinics, particularly in Florida, were buying from multiple distributors (which is a red flag for diversion). Ms. Collier found this surprising based on her experience in the pharmaceuticals industry.[1413]

When Mallinckrodt subsequently notified distributors that it would not pay chargebacks on sales to multi-distributor customers, Mallinckrodt failed to report any of the orders that gave rise to multi-distributor sales to the DEA as suspicious.[1414] Simply put, once Mallinckrodt identified pharmacies that were acquiring opioid products from multiple distributors, it moved quickly to refuse to pay chargebacks on those sales (thereby saving the company money), but failed to report these orders as suspicious to the DEA. Furthermore, by not employing the chargeback data the company had access to in a timely fashion, Mallinckrodt missed an opportunity to significantly improve its suspicious order monitoring program.

C. Chargebacks & DEA Enforcement Actions

During the review period, the DEA investigated and shut down several Mallinckrodt wholesalers including Harvard Drug Group; Masters Pharmaceuticals, Inc.; Keysource Medical; Kinray, LLC.; Value Drug, Inc.; and Sunrise Wholesalers, Inc. When taken together, the following pattern emerged:

1. These were not the Big Three distributors.
2. All were distributing high volumes of opioid products (e.g., Keysource Medical distributing 48 million dosage units to Florida customers).
3. All were distributing to multiple pharmacies (e.g., Kinray distributing to more than 20 New York pharmacies) which were filling opioid prescriptions for other than legitimate medical purposes; and

[1410] *See* Email from Karen Harper to herself (Nov. 18, 2010), MNK-T1_0000280835 (Harper notes indicating that she was currently working on adding chargeback data analysis to the SOM program.); Harper deposition at 355:22-356:22.

[1411] *See* K. Harper Deposition at 358:21-367:25; *see also* K. Harper Exhibit 22 (Mar. 29, 2010 email from Karen Harper to Carrie Johnson re chargeback information requests, MNK-T1_0000500657).

[1412] *See* G. Collier Deposition at 50:8-24 (Jan. 8, 2019).

[1413] *See id.* at 197:6-11 & Collier Ex. 15 (Nov. 11, 2010 email between G. Collier, S. Becker, and V. Borelli, MNK-T1_000418885) & Collier Ex. 16 (Sept. 2010) (Summary of customers sourcing more than 2 distributors for Oxy 30, MNK-T1_000418885).

[1414] G. Collier Deposition at 236:13-17.

4. All failed to report large numbers of suspicious orders to the DEA and failed maintain effective controls against the diversion of controlled substances.[1415]

In the case of each of these distributors that the DEA investigated and shut down, Mallinckrodt had similar data to the DEA, and where Mallinckrodt was the sole supplier of opioid products, the company had access to the same information as the DEA demonstrating significant diversionary activities by these wholesalers.

Mr. Becker, one of Mallinckrodt's NAMs, who had responsibility for many of the customers targeted by the DEA, related that:

(a) in the case of the Harvard Drug Group, he had the same information as the DEA regarding Mallinckrodt sales and could have conducted his own analysis on them, but did not because he was not suspicious of Harvard until he saw the press release indicating that its license was suspended;[1416]
(b) that he would have found it "alarming" that Mallinckrodt's chargeback data showed that Harvard, doing business as a vet supply company (First Veterinary Supply), supplied 12,487 orders of Oxy 15 and Oxy 30 to doctors, 92.4% of which went to the state of Florida, but that he was unaware of this information even though it was clear from the chargeback data;[1417]
(c) for Value Drug, he had access to the chargeback data showing Value Drug's sales to downstream customers, but never requested it from headquarters to evaluate them;[1418]
(d) with respect to Masters Pharmaceuticals, he had access to information regarding Masters' sales in the chargeback system, but did not recall having any suspicions about Masters until the DEA suspended its license;[1419]
(e) in the case of Kinray, he also had access to detailed information regarding Kinray sales and while he evaluated them, Kinray's activities did not raise any concerns for him.;[1420] and
(f) finally, with respect to Keysource, he conceded that the product monitoring group should have evaluated sales date for Keysource, but that he does not know if they ever did.[1421]

Mallinckrodt therefore had access to much, if not all, of the information possessed by the DEA, but Mallinckrodt failed to make use of that data.

[1415] *See* S. Becker Deposition Ex. 33 (June 15, 2010) (DEA Press Release re Harvard's suspension); S. Becker Deposition Ex. 36 (Sept. 15, 2015) (DEA Notice of Decision & Order re Masters); S. Becker Deposition Ex. 38 (Jun. 10, 2011) (Press Release re KeySource license suspension Becker Ex. 37 (Dec. 23, 2016) (DOJ Press Release re civil penalty levied against Cardinal); S. Becker Deposition Ex. 35 (Jun. 25, 2014) (DOJ Press Release re Value Drug settlement).

[1416] *See* S. Becker Deposition at 312:11-321:12.

[1417] S. Becker Deposition at 190:4-192:19.

[1418] *Id.* at 322:14-324:18.

[1419] *Id.* at 325:1-328:16.

[1420] *Id.* at 329:8-333:6.

[1421] *Id.* at 335:1-338:17.

14.6 Accountability - Consistent Enforcement

14.6.1 Even in the face of credible evidence, Mallinckrodt frequently failed to hold its distributors accountable for not having adequate SOM Programs

On August 23, 2011, Mallinckrodt met with the DEA in Washington D.C. During that meeting, the DEA told Mallinckrodt that it was under "tremendous pressure from Congress and the White House" to address the Florida oxycodone problem. The DEA also told Mallinckrodt that its distributors were not sufficiently validating the legitimacy of orders received from pharmacies in Florida.[1422] Therefore, a "disproportionate amount" of the company's 15 and 30 mg. oxycodone tablets were ending up in Florida pharmacies, and the DEA concluded that Mallinckrodt's distributors potentially had SOM programs that were inadequate.[1423]

After learning this from the DEA, Mallinckrodt met with Cardinal in September 2011 to discuss the potential problem pharmacies that had purchased large amounts of oxycodone 15 and 30 milligram dosages from Cardinal. Before the meetings with the DEA and Cardinal, Mallinckrodt had generated two "Top 20" lists of such pharmacies – the Top 20 from Florida and the Top 20 in the other states.[1424]

After Mallinckrodt and Cardinal met on October 2, 2011, Ms. Harper sent Cardinal revised Top 20 lists that apparently reflected the outcome of the joint review by and negotiations between Mallinckrodt and Cardinal.[1425] The net result was that after discussing these pharmacy situations with Cardinal, Mallinckrodt decided that 8 of the 20 Florida pharmacies should be removed from the chargeback restriction list. For the pharmacies outside of Florida, Mallinckrodt pared the list down to only 6 of the original 20 pharmacies. For the other 14, the notes indicated that the "Cardinal SOM file [was] not yet reviewed by Mallinckrodt," which suggests Cardinal had provided Mallinckrodt with information and the company was going to permit chargebacks for those pharmacies until it could review the file. Mallinckrodt and Cardinal set a target "cut off" date of October 14, 2011 to complete the review of the Top 20 pharmacies. [1426]

Mallinckrodt and Cardinal met again on October 13, 2011.[1427] This meeting appears to have resulted in an additional 7 Florida pharmacies being cleared for chargebacks by Mallinckrodt.[1428] This raised the total of cleared Florida pharmacies to 15 of the original Top 20 (75%) and 11 of 20 (55%) for the non-Florida pharmacies. In sum, Mallinckrodt's negotiations with Cardinal significantly eroded the effectiveness of

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1422 *See* Draft Notes for SOM Steering Committee Meeting (Sept. 28, 2011), MNK-T1_0002077756.

1423 *Id.*

1424 See Top 20 spreadsheet (Sept. 21, 2011), MNK-T1_000473333).

1425 *See* Email from K. Harper to Michael Moné, *et al.*, Re Revised Chargeback Restriction Listing for Pharmacies Purchasing Mallinckrodt Product from Cardinal, (Oct. 2, 2011), MNKT1_ 0000472004 (copying Mallinckrodt attorney Donald Lohman and others at Mallinckrodt).

1426 *See* Email from Jane Williams to Scott Decker *et al*, Re Revised Chargeback Restriction Listing for Pharmacies Purchasing Mallinckrodt Product from Cardinal, (Oct. 5, 2011), MNK-T1_0000471988.

1427 *See* Email from Donald Lohman to Nicholas Rausch Re Chargeback Status, (Oct. 17, 2011), MNK-T1_0000471975 (referencing prior week's meeting and clearing by Mallinckrodt of two pharmacies for chargeback reimbursement).

1428 *See* Spreadsheet Cardinal Health, (Oct. 13, 2011), MNK-T1_0000460617.

chargeback restrictions – the primary tool Mallinckrodt had used to ensure its distributors were cracking down on the problem pharmacies.

Mallinckrodt also purportedly "audited" all the previously listed distributors the DEA shut down. The CSP group described these audits as "high level," which appears to be an attempt to justify the lack of care in conducting them.[1429] Mallinckrodt did not inquire about the distributor's customers, even when it had chargeback data showing unusually high orders of oxycodone or inquire as to whether the distributors had cut off any pharmacies.[1430]

The Masters Pharmaceutical audit is an excellent example of Mallinckrodt's lack of diligence. In the Masters audit, completed in December 2010, Mallinckrodt concluded Masters possessed an "adequate" SOM process.[1431] Prior to that audit, Masters had identified a problem pharmacy, Brooks Pharmacy, which Masters had cut off in October 2010.[1432] However, apparently Mallinckrodt and Masters did not bother to discuss problem pharmacies such as Brooks during the audit because Mallinckrodt, through Cardinal, continued to supply Brooks with opioids after auditing Masters.[1433]

Furthermore, while the CSC often generated "indirect match" reports tracing Mallinckrodt opioid products to doctors and pharmacies after they had been shut down by the DEA, Mallinckrodt failed to use its data proactively to stop diversion.[1434] As highlighted by Mr. Becker, Mallinckrodt shipped to problematic distributors up until the time the distributors were shut down by the DEA.[1435] Even Ms. Harper acknowledged that pharmacies that been placed on a distributor's termination list were problematic, and that shipping orders to these pharmacies after placement on such as list "would not be indicative of an effective SOM program."[1436]

14.6.2 Mallinckrodt failed to hold employees accountable for being non-compliant and out of sync with its values.

This lack of accountability can be seen in several ways. First, Mallinckrodt made no effort to assess the extent to which its opioids sales goals and results were dependent on supplying irresponsible distributors and their remote customers. For example, at its national sales meeting for fiscal year 2011, Mallinckrodt celebrated that

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[1429] *See* Email from K. Harper to B. Ratliff Re Pete Kleissle, Oxy Investigation (July 27, 2009), MNK-T1_0000307203.

[1430] *See* K. Harper Deposition at 419:23-421:14.

[1431] *See* Masters Audit, *Controlled Substance Compliance/Suspicious Order Monitoring Distributor Customer Audit Checklist* at 5, (Dec. 8, 2010), MNK-T1_000029608.

[1432] *See* Harper Exhibit 29 (Oct. 20, 2011 email from Wayne Corona to Karen Harper re cut-off pharmacies, MNK-T1_0000311741).

[1433] *See* K. Harper Deposition at 417:20-419:12; *see also,* Harper Exhibit 30 (Brooks Pharmacy Monthly Total 15mg & 30mg Oxy "Sales Qty Govt UOM" 2010-2011, MNK-T1_0001519959 & MNK-T1_0001810303).

[1434] *See* Email chain between Carrie Johnson, Karen Harper and others (Sept. 6, 2011), MNK-T1_0000283884 (demonstrating that Indirect Match Reports were based on information re doctors and pharmacies that had already been shut down); Indirect Customer Match Report (Sept. 6, 2011), MNK-T1_0000283884.

[1435] *See* S. Becker Deposition Ex. 36 (Sept. 15, 2015 DEA Notice of Decision & Order re Masters); S. Becker Deposition Ex. 33 (June 15, 2010 DEA Press Release re Harvard's. suspension).

[1436] *See* K. Harper Deposition at 416:24-417:16.

generics sales were 99% of its plan and that everyone in the sales forces was "in the money," most between 100-115% of goals, but failed to even acknowledge that many of its major customers during 2011 had had their DEA licenses suspended or revoked.[1437] I have seen no evidence in the record that anyone at Mallinckrodt was subjected to disciplinary sanction or suffered any negative consequence for selling to any of the DEA suspended or revoked customers.

Second, the head of Mallinckrodt's compliance department, Karen Harper, testified that she offered her resignation after Mallinckrodt's settlement with the DOJ and DEA on the grounds that the deficiencies in Mallinckrodt's SOM program "happened on my watch," but her resignation was not accepted.[1438]

Third, in the case of Victor Borelli, customer Service Manager Cathy Stewart warned her superiors – Karen Harper and Bill Ratliff -- that the customer service representatives all said that "Borelli will tell them anything they want to hear just so he can get a sale." Furthermore, Mr. Ratliff testified that despite this warning, and despite not knowing whether Borelli was an "honest" or "reliable" person, no steps were taken to verify the information provided by Borelli.[1439]

Dr. Seth B. Whitelaw

President & CEO, Whitelaw Compliance Group, LLC.

[1437] *See Specialty Generics National Sales Meeting* presentation at 5 (Nov. 9, 2011), MNK-T1_0002450579; S. Becker Deposition at 152:1-154:3 (discussion of Exhibit 12).

[1438] *See* K. Harper Deposition at 98:05-13.

[1439] W. Ratliff Deposition at 284:13-285:10, 291:16-23 ("Q: Did – did anyone do anything to try to verify Mr. Borelli's information about Sunrise? A: I don't know. Q: In your opinion, should something have been done to try to verify this information? A: Based on what we know now, yes.")

Appendices

Appendix A: Opioid Public Health Crisis – A Brief Discussion

Figure 1: Opioid Public Health Crisis – A Brief Discussion

A recent House Energy and Commerce Committee Report declared that the "opioid epidemic is the worst drug crisis in America's history."[1440] Furthermore, the report noted that "[a]ccording to the Centers for Disease Control and Prevention, more than 351,000 lives have been lost to opioid overdoses since 1999, with no signs of abating."[1441] In fact, the report concluded the epidemic has a reached a point that it has "helped drive a decline in the U.S. life expectancy at a time when life expectancy is improving in many places around the world."[1442] Moreover, data from the CDC indicates that people who are addicted to opioids are 40 times more likely to subsequently become addicted to heroin.[1443]

The United States also is unique for the volume of opioid medicinal products used. A 2017 report by the International Narcotics Control Board noted that "[i]n 2016, the country with the highest consumption of hydrocodone continued to be the United States, with 33.4 tons, equivalent to 99.1 per cent of total global consumption."[1444] In that same report, it was noted that the United States consumed 72.9 per cent of the world's total of oxycodone for that same time period.[1445] However, the opioid crisis is not just about addiction and overdoses. It also impacts the patients who legitimately need access to opioids.

The opioid epidemic also is not a newly recognized public health crisis. As Judge Polster has written in this case, "[i]t is accurate to describe the opioid epidemic as a man-made plague, 20 years in the making."[1446] Also in August 2001, the House Subcommittee on Oversight and Investigations held a public hearing discussing the legitimate and illegitimate uses of oxycontin.[1447] Additionally, in December 2003, the United States General Accounting Office ("GAO") published for Congress on the abuse, use and diversion of OxyContin.[1448]

[1440] *See* U.S. House Energy & Commerce Committee Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, 115th Cong., 4 (Dec. 19, 2018).

[1441] *Id.* (quoting information provided the by Centers for Disease Control, citations omitted).

[1442] *Id.*

[1443] *See* Centers for Disease Control and Prevention, *Vital Signs; Today's Heroin Epidemic* (Jul. 2015)

[1444] *See* Int'l Narcotics Control Bd., *Narcotic Drugs: Estimated World Requirements for 2018*; *Statistics for 2016*, . 36 (2017).

[1445] Id. at 37.

[1446] *See* Amanda Bronstad, Opioid Judge Refuses to Dismiss Claims That Drug Companies Caused 'Man-Made Plague,' LAW.COM (Dec. 20, 2018 at 04:35 P.M.), https://www.law.com/2018/12/20/opioid-judge-refuses-to-dismiss-claims-that-drug-companies-caused-man-made-plague/ .

[1447] *See Oxycontin: Its Use and Abuse, Hearing Before the House Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce*, 107 Cong., (Aug. 28, 2001), https://www.govinfo.gov/content/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm

[1448] *See Oxycontin: Its Use and Abuse, Hearing Before the House Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce*, 107 Cong., (Aug. 28, 2001), https://www.govinfo.gov/content/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm; *see also* U.S. Gen'l Accounting Office, Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem, GAO-04-110 (Dec. 2003), https://www.gao.gov/new.items/d04110.pdf.

The State of Ohio also has been particularly hard-hit by this crisis. In 2010, a report by the Ohio Prescription Drug Abuse Task Force noted that "[i]n 2007, unintentional drug overdose surpassed motor vehicle crashes and suicide as the leading cause of injury death in Ohio for the first time on record."[1449] The report further noted that "prescription opioids are largely responsible for this alarming increase in drug overdose death rates."[1450] In 2012, Ohio was noted as being one of the top 10 states for pharmacy dispensing of oxycodone (#5), hydrocodone (#7), hydromorphone (#8), and oxymorphone (#7).[1451] For oxycodone, Ohio only lagged behind New York, California, Pennsylvania and Florida.[1452]

The opioid crisis is also unique in that activities in one location can have an impact on jurisdictions many miles or even states removed. Thus, the migration of opioids from the originating pharmacy to other cities, counties and states in some ways resembles Prohibition era bootlegging. Like alcohol bootlegging before it, opioid diversion takes a risk mitigation approach moving from areas with strong enforcement to areas that are weaker. Consequently, while Florida started out as "ground zero" for diversionary pharmacies, those pharmacies ultimately spread to others states such as Kentucky, West Virginia and Ohio.[1453]

With the purchase of the product tied to one location and consumption tied to another, opioid migration also resembles Prohibition era bootlegging. This phenomenon, the so-called "oxy express," describes the frequent trips made by thousands of individuals to states like Florida to purchase opioids easily and take them back to the State where they reside[1454] This phenomenon has been documented and commented on by both the DEA, as well as the distributors and manufacturers of opioid products.[1455]

By failing to monitor the number of opioid dosage units actually being distributed in a location versus what was legitimately needed, the lack of suspicious order due diligence on the part of opioid product manufacturers and distributors certainly has contributed to the ability of opioid products to move with relative ease between locales.

Therefore, as the objective evidence shows, the wide-spread use together with the accompanying abuse of prescription opioids constitutes an important, chronic public health crisis.

[1449] *See* OHIO PRESCRIPTION DRUG ABUSE TASK FORCE; FINAL REPORT TASK FORCE RECOMMENDATION, 19 (Oct. 1, 2010).

[1450] Id. at 20.

[1451] *See* Presentation by Krista Peck, Regulatory Update, 12 (circulated Jun. 10, 2014), MCKMDL00403517 at 00403529 (citing source as DEA Distributors Conference Oct. 2013).

[1452] *Id.*

[1453] *See* Presentation by McKesson Corporation, *Prescription Drug Abuse - The National Perspective,* 15 (2014), MCKMDL00407451 at 00407465.

[1454] *See* The 'Oxy Express': Florida's Drug Abuse Epidemic, NPR (Mar. 2, 2011), https://www.npr.org/2011/03/02/134143813/the-oxy-express-floridas-drug-abuse-epidemic; Pat Beall, *Florida cuts of oxy: Death, Devastation follow*, THE PALM BEACH POST, https://heroin.palmbeachpost.com/florida-cuts-off-oxycodone-death-devastation-follow/?ref=lowerTeases, (last visited Apr. 4, 2019).

[1455] *See e.g.,* Karen Harper Depo. at 91:9-92:19; Michael Oriente Depo. at 93:6-94:15.

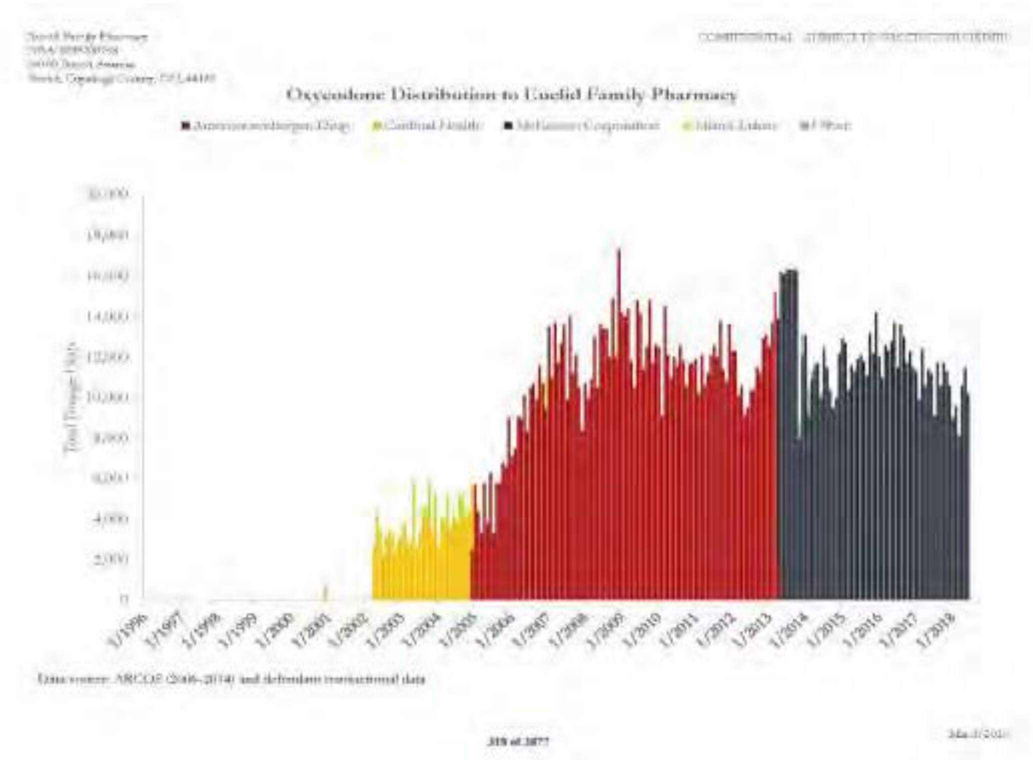


Figure 2: Oxycodone Distribution to Euclid by Distributor[1456]

AmerisourceBergen and McKesson were Euclid's Major Distributors from January 2005 to January 2018.

[1456] *See* Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated Mar 25, 2019 at 318 (Oxycodone Distribution to Euclid Family Pharmacy).

Appendix B: Applying the Standards

Figure 1: Table of Standard Elements Found in Policies and Procedures[1457]

General Elements	
• **Title**: identifies the subject • **Reference number**: useful for internal tracking • **Statement of purpose**: may provide citations to regulations • **Scope**: defines resources covered, such as all PHI or all confidential information including proprietary business information • **Definitions**: defines terms that have special meaning • **References**: lists any external sources of information or standards • **Effective date**: the date the policy or procedure was put into place	• **Review/revision date**: the date of any review and change. Policies should never be destroyed. If a policy is no longer applicable, it should be retired and placed in a permanent file. This is because it may be necessary for the organization or a member of the workforce to demonstrate that a previous action was or was not consistent with the old policy • **Authority and approval**: identifying who may authorize approval • **Rider**: may be used to authenticate receipt and agreement to abide by
Policy Statement	• **Measurable objectives and expectations**: these are the primary statements of the policy • **Responsibilities**: assigns duties for implementation • **Compliance enforcement**: describes how the policy will be monitored and enforced
Detailed Procedures Steps	• **Resources**: tools and other resources required to perform the procedure • **Detailed procedural steps**: a list, flowchart, or storyboard outlining the sequence of steps to perform • **Associated forms/screens**: illustrates data entry or retrieval • **Performance expectations**: quantity and quality standards

[1457] *See* Margret Amatayakul, *Practical Advice for Effective Policies, Procedures*, 74 J. OF *AHIMA*.4: 16A-D (Apr. 2003), http://library.ahima.org/doc?oid=59451#.XBfhIfZFwuW.

	associated with tasks

Figure 2: Controlled Substances Compliance

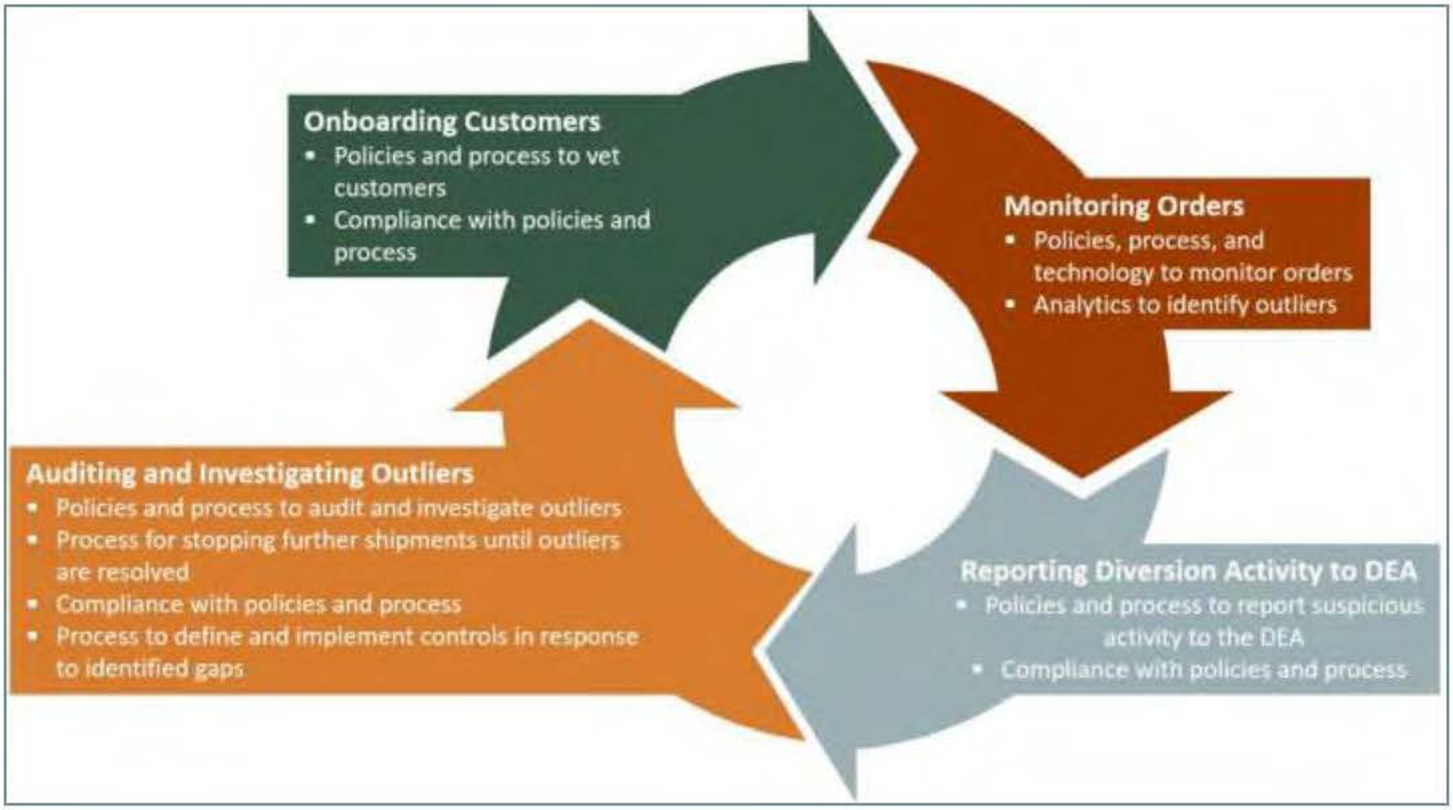
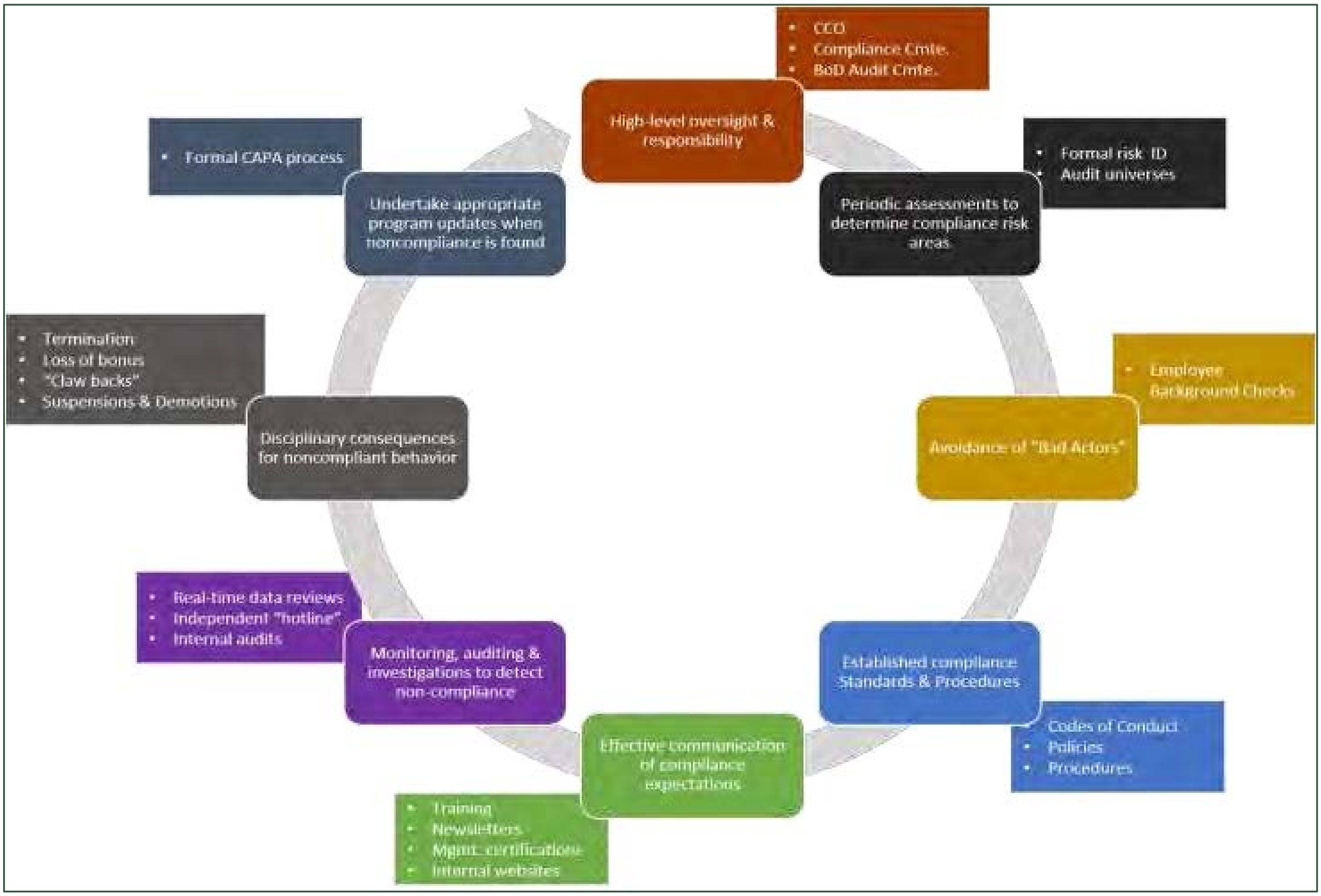


Figure 3: Corporate Compliance



Appendix C: McKesson Key Facts and Figures

Figure 1: McKesson Self-Reported Data Points

DATA	YEAR			
Item	**2014**	**2015**	**2016**	**2017**
Controlled Substance Program Headcount	30 [1458]			44[1459] (incl. 9 support members)
Number of Distribution Centers	30 [1460]			27[1461]
Number of Customers (Pharmacies)	~25,000 [1462]	34,816[1463]		>40,000[1464]
Number of Nightly Line Items Processed from Customers	1.2 million [1465]			
Number of Suspicious Orders Reported		230,000 [1466]	220,000 [1467]	145,000[1468]
Controlled Substances as Percentage of Enterprise-wide Sales		3.1-4.2% [1469]	3.1-4.2% [1470]	3.1-4.2% [1471]
Controlled Substances as a Percentage of U.S. Pharm.		4.3-5.2% [1472]	4.3-5.2% [1473]	4.3-5.2%[1474]

[1458] McKesson Corporation, Presentation to the USAO, Northern D. W. Va. and DEA, 9 (Mar. 12, 2014) MCKMDL00409116 ["USAO Presentation 2014"].

[1459] *See* ISMC Controlled Substances Monitoring Program Operating Manual, Version 1.3., 6, § 3.1, Figure 3, (Jan. 6, 2017), MCKMDL00395206 ["ISMC CSMP Manual 2017"].

[1460] *See* USAO Presentation 2014 at 4.

[1461] *See* MCK Teamsters Response at 1.

[1462] *See* USAO Presentation 2014 at 4.

[1463] *See* Presentation, *McKesson's Controlled Substances Monitoring Program - Regulatory Affairs Training*, 18 (undated), MCKMDL00336532; *but see* N. Hartle Deposition, 17:20-23 and 18:1-6 (Aug. 1, 2018) (Establishing via metadata that the training deck discussed in the De Gutierrez-Mahoney deposition was produced on December 31, 2015). Customer figure as of September 2015.

[1464] *See* MCK Teamsters Response at 12.

[1465] *See* USAO Presentation 2014 at 4.

[1466] *See* MCK Teamsters Response at 24.

[1467] *See* MCK Teamsters Response at 24.

[1468] *See* MCK Teamsters Response at 24.

[1469] *See* MCK Teamsters Response at 27.

[1470] *See* MCK Teamsters Response at 27.

[1471] *See* MCK Teamsters Response at 27.

[1472] *See* MCK Teamsters Response at 27.

[1473] *See* MCK Teamsters Response at 27.

DATA	YEAR			
Sales				

Headcount	YEAR			
	2014	2015	2016	2017
Controlled Substance Program Headcount	30 [1475]			44[1476] (incl. 9 support members)

Figure 2: McKesson Program Overview (Circa 2015)[1477]

[1474] *See* MCK Teamsters Response at 27.

[1475] McKesson Corporation, Presentation to the USAO, Northern D. W. Va. and DEA, 9 (Mar. 12, 2014) MCKMDL00409116.

[1476] *See* ISMC CSMP Manual 2017 at § 3.1, Figure 3, (Jan. 6, 2017), MCKMDL00395206.

[1477] *See* Presentation, *McKesson's Controlled Substances Monitoring Program - Regulatory Affairs Training*, at 24 (Reproduced by expert from slide).

Appendix D: Cardinal Health Key Facts and Figures

Figure 1: Various Data Points

DATA	YEAR						
Item	**2007-2012**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**
Total number of U.S. Customers with shipments suspended or terminated by Cardinal[1478]	~330						
W. Va. Suspicious Order Reports Submitted to the DEA[1479]	unknown	245	542	557	285	260	181
Dosage Units of Oxycodone & Hydrocodone Shipped to W. Va. (Millions)[1480]	174	36	31	32	40	34	--

1478 *See* W.Va. Red Flags Report at 246.

1479 *Id.* at 243.

1480 *Id.*

Figure 2: Table 5 -Customer Release Percentage[1481]

[redacted]

[1481] *See* Cardinal Health, *QRA SOM Customer Analytics General Work Instructions*, 15 (Sept. 20, 2013) (Appendix 5), CAH_MDL2804_00012244 at CAH_MDL2804_00012249, CAH_MDL2804_00012263.

Appendix E: AmerisourceBergen Key Facts and Figures

Figure 1: ABC 2009 Default Thresholds[1482]

Customer Type	Definition (Monthly Dollar Volume)	Oxycodone Threshold	Hydrocodone Threshold
Small Retail	Total <$100K	[redacted]	[redacted]
Medium Retail	Total >$100K and <$250K	[redacted]	[redacted]
Large Retail	Total >$250K	[redacted]	[redacted]

Category of Customers: (Average Retail Controlled Substances Ratio = 12%)

1. Low dollar volume and a low ratio of controlled substances
2. High dollar volume and a low ratio of controlled substances
3. Low dollar-volume (<$100K – small retail) and high [redacted] ratio of controlled substances
4. High dollar volume and controlled substances ratio.

Figure 2: ABC Diversion Control Policies and Procedures (SOPs)[1483]

Document	Policy or SOP	History & Comments
DCP – 12.1.0 Know Your Customer Due Diligence	Policy	Original – 1/1/2017
DCP – 12.1.10 New Customer Due Diligence	SOP	Original – 1/1/2017
DCP – 12.1.20 New Customer Communications	SOP	Original – 1/1/2017
DCP – 12.2.0 Order Monitoring Program	Policy	Original – 1/1/2017
DCP SOP – 12.2.10 OMP Methodology	SOP	Original – 1/1/2017
DCP SOP – 12.2.11 Product Family Risk Assessment	SOP	Original – 1/1/2017
DCP SOP – 12.2.12 Customer Peer Group Maintenance	SOP	Original – 1/1/2017
DCP SOP – 12.2.20 Identifying and Reporting Suspicious Orders	SOP	Original – 1/1/2017
DCP SOP – 12.2.30 Consumption Reviews	SOP	Original – 1/1/2017
DCP SOP – 12.2.40 OMP Annual Review	SOP	Original – 1/1/2017
DCP SOP – 12.2.50 Annual Audit	SOP	Original – 1/1/2017
DCP - 12.3.0 Ongoing Monitoring Policy	Policy	Original – 1/1/2017
DCP SOP - 12.3.10 Ongoing Monitoring Activities	SOP	Original – 1/1/2017
DCP SOP - 12.3.11 Targeted Pharmacy Visits	SOP	Original – 1/1/2017

[1482] *See* C. Zimmerman memorandum to E. Hazewski, *et al.*, *RVP Talking Points*, 1 (Jan. 19, 2009), ABDCMDL00000169.

[1483] *See* AmerisourceBergen Diversion Control Program Policies & Procedures, ABDCMDL00003367 to ABDCMDL00003429; D. Mays email to C. Conneely, *et al.*, *Diversion Control Policies* (Jan. 15, 2015) (Caroline Conneely was with FTI), ABDCMDL00251385 to ABDCMDL00251406.

Document	Policy or SOP	History & Comments
DCP SOP – 12.3.12 – Due Diligence Documentation	SOP	Original – 1/1/2017
DCP SOP – 12.3.20 Communicating Adverse Customer Actions	SOP	Original – 1/1/2017
CSRA 2.12 DCP - Order Monitoring Program	Policy	Original – 12/1/2005 Revised – 6/17/2013 (Document changed to reflect the change in operating systems as well as changes to address additional scrutiny from regulatory/enforcement agencies.)
CSRA 2.25 DCP – Retail Pharmacy Targeted Visits	Policy	Original – 10/1/2008 Revised – 6/17/2013 (Minor changes without changing the substance of policy)
CSRA 2.26 DCP - DEA Daily Reporting	Policy	Original – 10/21/2008
CSRA 2.30 DCP - Suspending CS Shipments to Customers	Policy	Original – 12/5/2013 (Marked "Draft")
CSRA 3.4 DCP - Customer Account Due Diligence	Policy	Original – 5/8/2007 Revised – 2/13/2013
CSRA 3.5 DCP - Customer Due Diligence Documentation	Policy	Original – 5/10/2013 (This is a new policy)
CSRA 3.9 DCP - GNPPN Accounts Terminated from PBMs	Policy	Original – 7/1/2011

Figure 3: West Virginia Suspicious Order Reports Submitted vs. Dosage Units Shipped[1484]

Suspicious Order Reports Submitted by AmerisourceBergen to the DEA											
2006	2007*	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
0	6	18	60	47	178	311	792	545	53	3	5
Number (in Millions) of Oxycodone and Hydrocodone Doses Shipped to West Virginia											
18.02	20.34	22.34	24.03	16.8	19.94	21.8	20.16	19.89	15.85	11.51	---

* AmerisourceBergen began to report and block suspicious orders in July 2007; thus, the number of suspicious orders reported in 2007 represents a partial year.

1484 *See* W.Va. Red Flags Report at 252.

Figure 4: Summit & Cuyahoga Suspicious Orders Reports Submitted[1485]

County	Year(s)	Number of Orders Reported
Summit	2007 to 2009	0
Summit	2010	4
Summit	2011	11
Summit	2012	13
Summit	2013	57
Summit	2014-2018	0
Cuyahoga	2007-2008	0
Cuyahoga	2009	5
Cuyahoga	2010	32
Cuyahoga	2011	55
Cuyahoga	2012	114
Cuyahoga	2013	155
Cuyahoga	2014	23
Cuyahoga	2015	3
Cuyahoga	2016-2018	0

[1485] *See* Spreadsheets ABDCMDL00383974, ABDCMDL00379674, ABDCMDL00383973, ABDCMDL00379673.

Appendix F: CVS Key Facts and Figures

Figure 1: CVS Entity Structure

Figure 2: CVS Logistics Organization

Appendix G: Walgreens Key Facts and Figures

Figure 1: Handling Suspicious Drug Orders

Reproduced below is the text of the Handling Suspicious Drug Orders "policy:"[1486]

Handling Suspicious Drug Orders

The Logistics and Planning Department sends the Suspicious Control Drug Orders report to all distribution centers. The report lists controlled drug orders that may be:

- Of unusual size for a store in its category
- Of unusual frequency for a store in its category
- Deviating from a normal pattern for a store in Its category

The distribution center must file all reports for five years.

Handling Suspicious Orders and Loss of Controlled Drugs

Policy

Distribution centers must file all Suspicious Control Drug Orders reports for five years. The Administration manager must complete the Report of Theft or Loss of Controlled Substances (DEA Form_106) when any of the following circumstances occur:

- A theft of controlled drugs, no matter how small. (Also file a police report.)
- A substantial loss (a full case or more, an entire repack, or a large dollar amount) of controlled drugs.
- All in-transit losses or thefts, as described above. If store personnel have already signed for the merchandise the pharmacy supervisor is responsible for completing the DEA form

The DEA form must be sent to the DEA, several Walgreens departments, and the local law enforcement agency if the loss was due to theft.

Note: Use U.S. certified mail when sending Form 106 to the DEA. Attach the receipt lo the distribution center copy.

[1486] *See* Walgreens, *Handling Suspicious Orders* (Feb. 15, 2005) (emphasis in the original), WAGFLDEA00001854 and WAGFLDEA00001855.

Figure 2: Review of CSR History[1487]

Phase	Key Points – Scope	Key Points – Identify/Flag selected orders	Key Points – Reduce order quantity for subset of flagged orders
1	• Deployed in August 2009 • Reviews WAG DC orders only • Review all Controlled Drug and PSE orders	• **Flags order based on by drug by store historical sales patterns, i.e. Tolerance threshold or order Frequency**	• No order reductions in Phase 1
2	• Deployed in September 2010 • No change to scope	• No change to Order Identification logic	• **Automatic reductions to orders that exceed Tolerance threshold**
3	• Deployed in June 2012 • **Relates vendor orders placed within 48 hours for same drug**	• Review and refinement of Tolerance/Frequency thresholds.	• No change in automatic order reduction logic
4	• Deployed in August 2012 • **Incorporates all Vendor orders and partial fills making them eligible for flagging and order reduction.**	• No change to Order Identification logic	• No change in automatic order reduction logic
5	• Deployed in November 2012 • Adds a Ceiling which limits the cumulative receipts of an item by a store	• Additional flags created for orders that are in excess of Ceiling for item/store combination • Remove Frequency threshold	• **Automatic reductions to orders that exceed either Tolerance or Ceiling threshold**

.

[1487] *See* Walgreens Presentation, *Controlled Substance Ordering – Evolution of Controlled Substances Ordering Process*, 3 (Oct. 11, 2012) (the system later came to be known as the Controlled Substance Order Monitoring and Prevention System), WAGMDL00667936 at WAGMDL00667938.

Appendix H: Mallinckrodt Key Facts and Figures

Figure 1: Controlled Substances Compliance SOPs

Document Title	Document Number	REVISION DATES 2008	2009	2010	2011	2012	2013	2015-18
Identification and Review of Peculiar Orders (precursors to C/S Comp. 3.0)[1488]	Draft #1 Draft #2 Draft #3 Draft #4 Draft #4	undated 5/13/08 6/12/08 7/08/08 7/15/08						
Identification and Review of Peculiar Orders[1489]	C/S Comp 3.0			10/29/10	1/04/11 3/28/11 8/08/11			
Modifications to Procedures for Identification and Review of Unusual Orders[1490]					12/08/11			
Identification, Investigation, and Reports of Controlled Substances Suspicious Orders[1491]	HZQS					9/20/12 10/18/12 11/01/12	3/05/13	08/17/15
New Customer Acct. Set-up & Existing Acct. Ongoing Review[1492]	C/S Comp. 2.0	6/09/08 (precursor)	7/01/09 11/04/09	3/02/10	1/04/11 3/28/11 8/08/11			
Customer Audit Program[1493]	C/S Comp. 4.0				1/04/11 3/28/11 8/08/11			
Identification & Review of	C/S Comp. 5.0				8/08/11			

[1488] *See* MNK-T1_0000273894, MNK-T1_0000268911, MNK-T1_0000419993, MNK-T1_0000296382, MNK-T1_0000263965.

[1489] *See* MNK-T1_0000264260, MNK-T1_0000264275, MNK-T1_0000264200, MNK-T1_0000259166.

[1490] *See* MNK-T1_0000571916.

[1491] *See* MNK-T1_0007728766, MNK-T1_0007476261, MNK-T1_0005620500, MNK-T1_0007732477, MNK-T1_0005621914.

[1492] *See* MNK-T1_0000264053, MNK-T1_0000264265, MNK-T1_0000264231, MNK-T1_0000264270, MNK-T1_0000264279, MNK-T1_0000264209, MNK-T1_0000259157.

[1493] *See* MNK-T1_0000264214, MNK-T1_0000264205, MNK-T1_0000259162.

Suspicious Customer Accts.[1494]								
Chargeback Restricting a Pharmacy[1495]	HZQS						9/05/13	8/5/17 (draft) 8/14/18 (SpecGx)
Reinstating a Chargeback Restricted Pharmacy[1496]						7/16/12	9/05/13	7/28/17 (draft)

The procedures in **blue** represent the keystone documents of Mallinckrodt's suspicious order monitoring program.

Figure 2: "Peculiar Orders" Definition Changes

Definition	Document Title	Doc. Number	Date
"A controlled substance order that meets an internal established criterion that will not be shipped pending further review by DEA Compliance."	Identification and Review of Peculiar Orders (precursors to C/S Comp. 3.0)	Draft #1	undated[1497]
(Same as Draft #1)		Draft #2	5/13/08[1498]
"A controlled substance order that meets an internal established criterion that will be placed on hold pending further review by DEA Compliance."		Draft #3	6/02/08[1499]
(Same as Draft #3)		Draft #4	7/08/08[1500]
(Same as Draft #3)		Draft #4	7/15/08[1501]
"Controlled substance order that meets internal established criteria of 3X the average amount of product ordered during the previous 12 months by DEA reporting class."	Identification and Review of Peculiar Orders	C/S Comp 3.0	10/29/10[1502]
(Same as 10/29/10 version)	Identification and Review of Peculiar Orders	C/S Comp 3.0	1/04/11[1503]
"Mallinckrodt direct customer controlled substance order that meets internal established criteria of 3X the average amount of product ordered during the previous 12 months by DEA reporting class."	Identification and Review of Peculiar Orders	C/S Comp 3.0	3/28/11[1504]
(Same as 3/28/11)	Identification and Review of	C/S Comp 3.0	8/08/11[1505]

1494 *See* MNK-T1_0000259153.

1495 *See* MNK-T1_0000511225; MNK-T1_0007732565; MNK-T1_0004155830.

1496 *See* MNK-T1_0007732447; MNK-T1_0007732532; MNK-T1_0007732621

1497 MNK-T1_0000273894

1498 MNK-T1_0000268911.

1499 MNK-T1_0000419993.

1500 MNK-T1_0000296382.

1501 MNK-T1_0000263965.

1502 MNK-T1_0000264260.

1503 MNK-T1_0000264275.

1504 MNK-T1_0000264200.

Definition	Document Title	Doc. Number	Date
	Peculiar Orders		
(Not Mentioned)	Modifications to Procedures for Identification and Review of Unusual Orders		12/8/11[1506]
"A standard algorithm with respect to volume which sets a monthly limit at: (a) 2.5X the average number of orders of a product during the previous 18 months by the customer and (b) 2.5X the average volume of product ordered during the previous 18 months by the customer."	Identification, Investigation, and Reports of Controlled Substances Suspicious Orders	HZQS	11/01/12[1507]

[1505]MNK-T1_0000259166.

[1506]MNK-T1_0000571916.

[1507]MNK-T1_0005620500

Appendix I: List of Materials Considered

A. Defendant Production Documents

CAH_MDL_PRIORPROD_DEA07_01185382
CAH_MDL_PRIORPROD_DEA12_00011059
HDS_MDL_00002032
Acquired_Actavis_00441354
CAH_MDL2804_01431074
WAGMDL00490963
WAGMDL00493697
WAGMDL00493694
WAGMDL00387635
WAGMDL00387641
WAGMDL00709395
WAGMDL00749381
WAGMDL00010887
WAGMDL00751821
WAGMDL00751871
WAGMDL00777158
WAGMDL00414048
WAGMDL00303305
WAGMDL00060486
WAGMDL00400358
WAGMDL00400360
WAGMDL00101723
WAGMDL00624503
WAGMDL00659801
WAGMDL00660331
WAGMDL00659270
WAGMDL00674280
WAGMDL00574824
WAGMDL00358471
WAGMDL00400357
WAGMDL00700240
WAGMDL00709508
WAGMDL00709510
WAGMDL00477975
WAGMDL00107532
WAGMDL00415348
WAGMDL00757193
WAGMDL00757759
WAGMDL00757762
WAGMDL00757788
WAGFLDEA00001854
WAGFLDEA00000027
WAGFLDEA00000028
WAGFLDEA00000117
WAGMDL00325170
WAGMDL00325129
WAGMDL00667936
WAGMDL00658227
WAGMDL00246016
WAGMDL00010925
WAGMDL00010926
WAGMDL00010927
WAGMDL00010928
WAGMDL00037093
WAGMDL00037094
WAGMDL00095316
WAGMDL00095317
ALLERGAN_MDL_03755273
MCKMDL00478906
MCKMDL00478910
MNK-T1_0001454856
WAGFLDEA00000846
WAGFLDEA00000852
WAGMDL00006645
WAGMDL00021425
WAGMDL00035669
WAGMDL00044765
WAGMDL00077015
WAGMDL00077016
WAGMDL00102390
WAGMDL00107267
WAGMDL00107557
WAGMDL00113808
WAGMDL00119539
WAGMDL00119542
WAGMDL00183798
WAGMDL00237698
WAGMDL00245867
WAGMDL00254645
WAGMDL00254649
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- Donald Walker Spoke Profile, http://www.spoke.com/people/donald-walker-3e1429c09e597c10039327ad (last accessed Dec. 11, 2018)
- Gilberto Quintero LinkedIn Profile, https://www.linkedin.com/in/gilbertoquintero/ (last accessed Jan. 29, 2019).
- Debbie Schwartz LinkedIn Profile, https://www.linkedin.com/in/debbieswartz/ (last accessed Jan. 26, 2019).
- Chris Zimmerman LinkedIn Profile, https://www.linkedin.com/in/chriszimmerman/
- Ed Hazewski LinkedIn Profile, https://www.linkedin.com/in/edwardhazewski/
- Nathan Elkins LinkedIn Profile, https://www.linkedin.com/in/nathan-elkins-8a1b0718/ (last accessed Mar. 16, 2019).
- Diane Nobles LinkedIn Profile https://www.linkedin.com/in/dbnobles/ (last accessed Feb. 12, 2019)
- John Buckley LinkedIn Profile, https://www.linkedin.com/in/jmbuckleycco/ (last accessed Feb. 26, 2019)
- David Falkowski LinkedIn Profile, https://www.linkedin.com/in/david-f-45037626/ (last accessed Feb. 26, 2019)
- Laura Merton LinkedIn Profile, https://www.linkedin.com/in/lauramerten/ (last accessed Feb. 12, 2019)
- Matthew D'Ambrosio LinkedIn Profile, https://www.linkedin.com/in/mattdambrosio/ (last accessed Feb. 12, 2019).

F. Defendant Discovery Responses; MDL No. 2804 *IN RE: National Prescription Opiate Litigation*

- AmerisourceBergen's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests (Mar. 4, 2019)

- Cardinal Health Inc.'s Third Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests (Mar. 4, 2019)
- CVS RX Services, Inc.'s and CVS Indiana L.L.C.'s Objections and Responses to Plaintiffs' (First) Combined Discovery Requests to National Retail Pharmacy Defendants (Nov. 30, 2018)
- McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests (Mar. 4, 2019)
- McKesson Corporation's Third Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests Nos. 2 and 3 (March 29, 2019)
- Walgreen Co. and Walgreen Eastern Co.'s Second Amended Objections and Responses to Plaintiffs' First Set of Interrogatories (Mar. 4, 2019)
- Mallinckrodt's Supplemental Responses and Objections to Interrogatory Nos. 1, 5, 7, 8, 9, 16, 21, 22, 23, 27, 30, 31, 32, 33, and 35 (Jan. 30, 2019)
- Mallinckrodt's Supplemental Responses and Objections to Interrogatory Nos. 1-5, 7-9, 11-13, 15-16, 18-19, 21-22, 25-26, and 29-35 (Mar. 5, 2019)

G. Corporate Witness Depositions

- Deposition of Nathan Elkins + Exhibits (11/14/2018) (AmerisourceBergen)
- Deposition of Edward Hazewski + Exhibits (10/25/2018) (AmerisourceBergen)
- Deposition of David May + Exhibits (8/4/2018) (AmerisourceBergen)
- Deposition of Steve Mays + Exhibits (10/24/2018) (AmerisourceBergen)
- Deposition of Chris Zimmerman + Exhibits (8/3/2018) (AmerisourceBergen)
- Deposition of Steve Mays - Volume II + Exhibits (2/8/2019) (AmerisourceBergen)
- Deposition of Marcelino Guerreiro + Exhibits (4/3/2019) (AmerisourceBergen)
- Deposition of Mark Hartman + Exhibits (11/15/2018) (Cardinal)
- Deposition of Kim Howenstein + Exhibits (1/10/2019) (Cardinal)
- Deposition of Stephen Reardon+ Exhibits (11/30/2018) (Cardinal)
- Deposition of Chris Lanctot + Exhibits (10/10/2018) (Cardinal)
- Deposition of Steve Morse + Exhibits (12/13/2018) (Cardinal)
- Deposition of Christopher Forst + Exhibits (1/22/2019) (Cardinal)
- Deposition of Jennifer Norris + Exhibits (8/7/2018) (Cardinal)
- Deposition of Eric Brantley + Exhibits (11/27/2018) (Cardinal)
- Deposition of Nick Rausch + Exhibits (11/16/2018) (Cardinal)
- Deposition of Steve Lawrence + Exhibits (1/4/2019) (Cardinal)
- Deposition of Kelly Baker + Exhibits (1/24/2019) (CVS)
- Deposition of Aaron Burtner + Exhibits (1/17/2019) (CVS)
- Deposition of Frank Devlin + Exhibits (1/10/2019) (CVS)
- Deposition of Terrance Dugger + Exhibits (1/23/2019) (CVS)
- Deposition of Shauna Helfrich + Exhibits (1/10/2019) (CVS)
- Deposition of Pam Hinkle + Exhibits (1/24/2019) (CVS)
- Deposition of Sherri Hinkle + Exhibits (1/25/2019) (CVS)
- Deposition of Ronald Link + Exhibits (12/11/2018) (CVS)
- Deposition of Gary Milikan + Exhibits (1/11/2019) (CVS)
- Deposition of John Mortelliti + Exhibits (1/23/2019) (CVS)
- Deposition of Mark Nicastro + Exhibits (12/6/2018) (CVS)
- Deposition of Amy Propatier + Exhibits (11/29/2018) (CVS)
- Deposition of Craig Shiavo + Exhibits (1/17/2019) (CVS)
- Deposition of Dean Vanelli + Exhibits (1/16/2019) (CVS)

- Deposition of Mark Vernazza + Exhibits (11/20/2018) (CVS)
- Deposition of Ellen Wilson + Exhibits (1/24/2019) (CVS)
- Deposition of Dave Gustin + Exhibits (8/17/2018) (McKesson)
- Deposition of Michael Oriente + Exhibits (7/19/2018) (McKesson)
- Deposition of Blaine Snider + Exhibits (11/8/2018) (McKesson)
- Deposition of Gary Hilliard + Exhibits (1/10/2019) (McKesson)
- Deposition of Donald Walker + Exhibits (1/10/2019) (McKesson)
- Deposition of Nate Hartle (30(b)(6)) + Exhibits (7/31/2018) (McKesson)
- Deposition of Nate Hartle + Exhibits (8/1/2018) (McKesson)
- Deposition of William De Gutierrez-Mahoney + Exhibits (11/28/2018) (McKesson)
- Deposition of Gene Cavacini + Exhibits (1/25/2019) (McKesson)
- Deposition of Gary Boggs + Exhibits (7/19/2018) (McKesson)
- Deposition of Gary Boggs + Exhibits (1/17/2019) (McKesson)
- Deposition of Tracy Jonas + Exhibits (11/15/2018) (McKesson)
- Deposition of Tom McDonald + Exhibits (12/07/2018) (McKesson)
- Deposition of Micheal Bishop + Exhibits (1/09/2019) (McKesson)
- Deposition of Stephen Bamberg + Exhibits (12/14/2018) (Walgreens)
- Deposition of Wayne Bancroft + Exhibits (1/10/2019) (Walgreens)
- Deposition of Edward Bratton + Exhibits (11/30/2018) (Walgreens)
- Deposition of Edward Bratton (30 (b)(6)) + Exhibits (12/16/2018) (Walgreens)
- Errata For Deposition of Edward Bratton (30 (b)(6)) (12/16/2018) (Walgreens)
- Deposition of Christopher Dymon + Exhibits (1/25/2019) (Walgreens)
- Deposition of Barbara Martin + Exhibits (1/25/2019) (Walgreens)
- Deposition of John Merritello + Exhibits (1/18/2019) (Walgreens)
- Deposition of Steve Mills + Exhibits (11/8/2018) (Walgreens)
- Deposition of Denman Murray Jr. + Exhibits (1/15/2019) (Walgreens)
- Deposition of Natasha Polster + Exhibits (1/23/2019) (Walgreens)
- Deposition of Eric Stahmann + Exhibits (10/16/2018) (Walgreens)
- Deposition of Rex Swords + Exhibits (12/21/2018) (Walgreens)
- Deposition of Deborah Bish+ Exhibits (2/1/2019) (Walgreens)
- Deposition of Jennifer Diebert + Exhibits (1/24/2019) (Walgreens)
- Deposition of John Adams + Exhibits (1/31/2019) (Mallinckrodt)
- Deposition of Steven Becker + Exhibits (12/19/2018) (Mallinckrodt)
- Deposition of Victor Borelli + Exhibits (11/29/2018) (Mallinckrodt)
- Deposition of Ginger Collier + Exhibits (1/08/2019) (Mallinckrodt)
- Deposition of John Gillies + Exhibits (2/07/2019) (Mallinckrodt)
- Deposition of Karen Harper + Exhibits (1/15/2019) (Mallinckrodt)
- Deposition of Kate Neely (Muhlenkamp) + Exhibits (1/08/2019) (Mallinckrodt)
- Deposition of William Ratliff + Exhibits (12/19/2018) (Mallinckrodt)
- Deposition of James Rausch + Exhibits (11/16/2018) (Mallinckrodt)
- Deposition of Tiffany Rowley-Kilper + Exhibits (2/09/2019) (Mallinckrodt)
- Deposition of Cathy Stewart + Exhibits (12/11/2018) (Mallinckrodt)
- Deposition of Hugh O'Neill + Exhibits (3/13/2019) (Mallinckrodt)

H. Third-Party Witness Depositions

- Deposition of Kyle Wright – Volume I + Exhibits (2/28/2019) (DEA)
- Deposition of Kyle Wright – Volume II + Exhibits (3/4/2019) (DEA)

- Deposition of Demetra Ashley + Exhibits (3/15/2019) (DEA)

I. Other Non-Publicly-Available Materials

- Cardinal Health Organization Chart 2012-2015 (P1.4592)
- Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 218-221, 1944-1947 (Oxycodone and Hydrocodone Distribution to CVS Pharmacy #03322 by Cardinal Health and CVS; Opioid Shipments to AR7531418 by Distributor; Ohio CVS Stores, LLC, AR7531418 Total Dosage Units and Total MME by Drug Family)
- Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 1416-1419, 3216-3219 (Oxycodone and Hydrocodone Distribution to CVS Pharmacy #04800 by Cardinal Health and CVS; Opioid Shipments to BR0287234 by Distributor; Ohio CVS Stores, LLC, BR0287234 Total Dosage Units and Total MME by Drug Family)
- Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 51, 136 (Total Dosage of Oxycodone and Hydrocodone Shipped by Cardinal Health to Cuyahoga County, Ohio (Jan. 1996 to April 2018))
- Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 93, 178 (Total Dosage of Oxycodone and Hydrocodone Shipped by Cardinal Health to Summit County, Ohio (Jan. 1996 to April 2018))
- Appendix 9 to Expert Report of Craig J. McCann, Ph.D., CFA dated March 25, 2019 at 318 (Oxycodone Distribution to Euclid Family Pharmacy)

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DR. SETH B. WHITELAW

PROFESSIONAL SUMMARY

Dr. Whitelaw has more than 25 years of industry experience in the life sciences and healthcare sectors, as an attorney, compliance officer and consultant. His career has focused on food and drug law and corporate governance, as well as designing and running compliance programs within medical devices, pharmaceutical sales and marketing, and pharmaceutical R&D. He is a licensed food and drug attorney, with a doctorate in Health Law. His forte is designing, building and running life science compliance programs from a "blank sheet of paper."

LICENSES & INTERNSHIPS

Licensed to Practice Law in the Commonwealths of Pennsylvania (2004) and Virginia (1988)

Food and Drug Law Institute Fellowship (1988)

Internship with U.S. Food and Drug Administration, Office of Chief Counsel (1988-1989)

Internships with Grocery Manufacturers Association (GMA), Washington, D.C.

EXPERIENCE

WHITELAW COMPLIANCE GROUP, LLC., PHILADELPHIA, PA
President & CEO, April 2015 – Present

Focused exclusively on small to medium-sized FDA-regulated companies, the Whitelaw Compliance Group provides practical, pragmatic compliance and integrity services that are tailored to each regulated company to help them grow and achieve sustainable integrity.

Responsible for designing, developing and implementing a med tech tailored compliance program to address compliance risks, including FCPA and UK Bribery Act issues.

POLICY & MEDICINE COMPLIANCE UPDATE, COLUMBIA, MD
Editor, October 2015 – Present

Formerly Life Science Compliance Update. Oversees the editorial content, assembly and monthly publication providing comprehensive, up-to-date compliance information for pharmaceutical, biotechnology, and device manufacturers. Writes articles on emerging life sciences issues for the publication.

MITCHELL HAMLINE SCHOOL OF LAW, ST. PAUL, MN
Senior Fellow and Adjunct Professor, Life Sciences Compliance, September 2016 – Present

Oversaw, designed and taught Legal Compliance Essentials for Drug, Device and Biotech Companies (J-Term 2017)

Co-teaching Health Care Compliance Skills (Fall 2017 & Spring-Fall 2018)

MISONIX, INC., FARMINGDALE, NY
Interim Chief Compliance Officer, December 2016 – June 2017

Interim Chief Compliance Officer for Misonix, Inc., which specializes in the development and commercialization of ultrasonic surgical devices for neurosurgical, spinal, advanced wound care, and general surgery procedures. Responsible for the day-to-day implementation and operation of the Compliance Program including compliance efforts involving interactions with health care professionals and anti-bribery/anti-corruption.

- Delivered over $165K in sales, from Chinese distributors as a result of overseeing and managing enhanced third-party due diligence and contracting process.

DELOITTE & TOUCHE LLP., PHILADELPHIA, PA
Director, October 2011 – April 2015

Led the Advisory Practice's transparency team assisting U.S. and other global medical device and pharmaceutical clients in developing effective processes and operating approaches to meet both U.S. Sunshine Act requirements, as well as other global requirements (e.g., France, Japan and EFPIA).

- Consistently delivered more than $1M in sales each year.

Advised various multinational clients on structuring a global compliance function including work plan prioritization.

Assisted a client with medical device, pharmaceutical, and consumer products units to develop a streamlined and strategic Medical Affairs department to support its globally growing business.

Conducted multiple internal audits for clients in both the R&D and third-party oversight areas working with global teams.

Served as Editor-in-Chief and contributing author for Deloitte's @Regulatory bulletins from 2013-2015

GLAXOSMITHKLINE, PHILADELPHIA, PA
Compliance Officer, Global R&D, January 2001 – October 2011

Successfully designed, developed, implemented and led the corporate compliance infrastructure, including integrating internal audit with compliance, for GSK's global R&D operations where none had existed previously.

Founded and supported the compliance infrastructure for GSK's new R&D China site in Shanghai.

Provided compliance oversight and support to sites in U.S, U.K. China, Italy, Spain, France and Croatia with small (9) central staff on a broad range of topics including conflicts of interest, anti-kickback, FCPA, false claims, use of human biological samples, transparency, etc.

Created and implemented policies, systems and processes ahead of industry practice to reduce the risk from perceived improper influence with healthcare professionals, especially in countries with national health insurance programs.

Successfully negotiated with various regulatory authorities to resolve compliance issues.

Led compliance efforts surrounding GSK's voluntary disclosure of research payments to healthcare professionals and healthcare institutions (e.g., transparency).

Helped lead R&D's efforts to prepare for impending Corporate Integrity Agreement

SMITHKLINE BEECHAM PHARMACEUTICALS, PHILADELPHIA, PA
Legal Compliance Officer, January 1997 – January 2001

Successfully designed and implemented the corporate compliance infrastructure for the U.S. and Canadian commercial operations where none had existed previously and co-led the integration of the departments during the Glaxo Wellcome/SmithKline merger.

Created and implemented policies, systems and processes ahead of industry practice to reduce the risk from perceived improper influence with healthcare professionals (e.g., banning gifts).

Successfully help lead the efforts to enhance SmithKline's sample accountability (PDMA) program.

C.R. BARD, INC., MURRAY HILL, NJ
Senior Attorney & Compliance Coordinator, January 1991 - January 1997

Created and implemented Bard's original corporate medical device compliance program to meet the requirements of the Federal Sentencing Guidelines and Bard's Plea Agreement with the U.S. Department of Justice and served as Bard's first Compliance Officer post settlement.

Successfully directed and managed Bard's company-wide document production efforts for the U.S. v. C.R. Bard, Inc. litigation resulting in the production of over 750,000 responsive pages. Worked directly with both the AUSA's Office in Boston as well as FDA's Office of Criminal Investigation.

Oversaw and updated Bard's records retention program.

Created, managed and implemented a Legal Audit Program to provide the Corporation with a concrete evaluation of its overall compliance with both the federal FDA regulatory scheme (e.g., 501(k) compliance, Quality System requirements) and its internal policies. This program was successfully integrated with Bard's already established internal and quality auditing programs.

Provided legal counsel on various medical device regulatory matters including those issues involving FDA, EPA and OSHA (e.g., custom devices, consumer preference testing, medical device reports, FDA-483 and Warning Letter responses)

FD Inc., Washington, D.C.
Head of Sales and Marketing, March 1990- January 1991

Sales and marketing of food and drug statutory, administrative and regulatory materials on compact disk, with direct responsibility for developing and implementing both short and long-term marketing strategies for the company.

Fox, Bennett & Turner., Washington, D.C.
Associate, May 1989- March 1990

Compliance counseling and opinion drafting on food, drug and environmental issues, particularly safety and risk assessment.

EDUCATION

WIDENER UNIVERSITY SCHOOL OF LAW, WILMINGTON, DE
2011 – S.J.D., Health Law

GEORGE WASHINGTON UNIVERSITY LAW SCHOOL, WASHINGTON, D.C.
1989- LL.M., Administrative Law

WASHINGTON & LEE UNIVERSITY, SCHOOL OF LAW, LEXINGTON, VA
1988 – J.D.

BOWDOIN COLLEGE, BRUNSWICK MAINE
1985- A.B., History (*Cum laude)*

Publications List

PUBLICATIONS

- Whitelaw, Seth; Fiorentino, Nicodemo; and O'Leary, Jennifer "Drug Pricing—The Next Compliance Waterloo," Mitchell Hamline Law Review: 2018 Vol. 44: Iss. 4, Article 2. Available at: https://open.mitchellhamline.edu/mhlr/vol44/iss4/2.
- Schroeder, Whitelaw, Makosch, Adapt or Perish -Can Stem Cell Therapies Achieve Their Potential for Delivering Optimal, Cost-Effective Clinical Outcomes in an Evolving Regulatory Framework?, Life Science Compliance Update Special Supplement (Aug. 2018)
- Whitelaw, et al., The Day After Tomorrow - The Drug Pricing Chorus Grows Louder, 4.4 Life Science Compliance Update 1 (Apr. 2018)
- “Missing the Market: Government Standards Are Undermining Compliance Efforts in Smaller Life Science Companies,” Attorney at Law Magazine, Minnesota Ed. (Mar. 2018)
- Whitelaw, et al., A Bright Future or Unfulfilled Promise – An Update on Biosimilars and Their Prospects for Contributing to Meaningful Cost Reduction, 4.3 Life Science Compliance Update 13 (Mar. 2018).
- “One Purpose to Rule Them All – A Resounding ‘Yes’ According to the District Court in U.S. ex rel. Cairns,” Life Science Compliance Update, Vol. 4.2 (Feb. 2018).
- “On a Collision Course – FDA Clinical Investigator Disclosure and Open Payments,” Life Science Compliance Update, Vol. 2.9 (Sep. 2016).
- “The Board of Directors’ Role in Pharmaceutical Compliance,” Pharmaceutical Compliance Monitor (Dec. 10, 2012).
- Evaluating IRB’s and Their Roles, 16 Food, Drug, Cosmetic and Medical Device Law Digest
- “How Can FDA Improve Its Financial Disclosure Rules for Clinical Investigators in this New Era of Transparency?”, Food and Drug Law Institute Policy Forum (Jun. 2011).
- “Proposition 65 v. Industry: David Against Goliath or a Misled Public Run Amok?,” 44 Food Drug Cosmetic Law Journal 677
- “FDA Publishes The New UDI Regulations – Will You Be Ready?,” Deloitte (Oct. 2013) http://www.deloitte.com/view/en_US/us/Industries/health-care-providers/9026855ddef61410VgnVCM1000003256f70aRCRD.htm)

- "Four Actions You Can Still Take to Begin Sunshine Act Compliance", Deloitte (Aug. 2013) http://www.deloitte.com/view/en_US/us/Insights/centers/center-regulatory-strategies/crs-blog/d8f713e7e1c90410VgnVCM2000003356f70aRCRD.htm)
- "Time Crunch - Physician Payments Sunshine Act," Deloitte (Jun. 2013) (http://www.deloitte.com/view/en_US/us/Services/audit-enterprise-risk-services/governance-regulatory-risk-strategies/9a0af1b41c08f310VgnVCM1000003256f70aRCRD.htm)
- "The Board of Directors' Role in Pharmaceutical Compliance," Pharmaceutical Compliance Monitor (Dec. 10, 2012), http://www.pharmacompliancemonitor.com/the-board-of-directors-role-in-pharmaceutical-compliance-2/3677/
- Practicing Avoidance: Navigating Qui Tam and Consent Decrees, Pharmaceutical Compliance Monitor (Jan. 9, 2012), http://www.pharmacompliancemonitor.com/practicing-avoidance-navigating-qui-tam-consent-decrees/#more-996.
- How Can FDA Improve Its Financial Disclosure Rules for Clinical Investigators in this New Era of Transparency?, Food and Drug Law Institute Policy Forum (June 2011)

ONLINE CONTENT (EDITOR)

- Policy & Medicine Compliance Update Vol. 5.4 April 2019.
- Policy & Medicine Compliance Update Vol. 5.3 March 2019.
- Policy & Medicine Compliance Update Vol. 5.2 February 2019.
- Policy & Medicine Compliance Update Vol. 5 January 2019.
- Policy & Medicine Compliance Update Vol. 4.12 December 2018.
- Policy & Medicine Compliance Update Vol. 4.11 November 2018.
- Policy & Medicine Compliance Update Vol. 4.10 October 2018.
- Policy & Medicine Compliance Update Vol. 4.9 September 2018.
- Adapt or Perish Can Stem Cell Therapies Achieve Their Potential For Delivering Optimal Cost-Effective Clinical Outcomes In an Evolving Regulatory Framework?, Policy & Medicine Life Science Compliance Special Supplement Vol. 4.8 August 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.8 August 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.7 July 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.6 June 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.5 May 2018.

- Policy & Medicine Life Science Compliance Update Vol. 4.4 April 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.3 March 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.2 February 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.1 January 2018.
- Policy & Medicine Life Science Compliance Update Vol. 3.12 December 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.11 November 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.10 October 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.9 September 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.8 August 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.7 July 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.6 June 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.5 May 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.4 April 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.3 March 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.2 February 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.1 January 2017.
- Policy & Medicine Life Science Compliance Update Vol. 2.12 December 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.11 November 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.10 October 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.9 September 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.8 August 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.7 July 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.6 June 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.5 May 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.4 April 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.3 March 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.2 February 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.1 January 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.0 December 2015.
- Policy & Medicine Life Science Compliance Update Vol. 1.9 November 2015.

- Compliance for the Common Man Policy & Medicine Life Science Compliance Update Vol. 1.5 July 2015.

REPRESENTATIVE SPEAKING ENGAGEMENTS

- Guest lecturer at Temple University, Ursinus College, Medical Devices Section, Food and Drug Law, Rutgers-Camden Law School
- Mitchell Hamline's Health Law Institute Symposium - Hot Topics in Healthcare Compliance (2018)
- CBI 2nd Annual Drug Pricing Transparency Conference (2018)
- CBI Annual Pharmaceutical Compliance Congress (multiple years) Pharmaceutical Regulatory and Compliance Congress (multiple years)
- Mitchell Hamline School of Law, National Speaker Series (Oct. 2016)
- DIA Marketing Pharmaceuticals (2014)
- Sixth National Disclosure Summit (2014)
- Pharmaceutical Regulatory and Compliance Congress (2013)
- Food and Drug Law Institute Advertising and Promotion Conference (2013)
- CBI 9th Annual Pharmaceutical Accounting and Reporting Congress (2013)
- AdvaMed Conference (2012)
- CBI 9th Annual Pharmaceutical Compliance Congress (2012)
- FDLI US-China Food and Drug Law (2011)
- Food and Drug Law Institute Annual Conference (2011)
- ACI 11th National Forum on Fraud & Abuse in Sales & Marketing (2011)
- Widener Law 2d Annual Regulatory Compliance Program (2010)
- Marcus Evans Commercial Compliance for Pharmaceutical & Medical Device Companies (2010)
- CBI Clinical R&D Compliance Forum (2010)
- Drug Information Association 46th Annual Meeting (2010)
- Pharma Compliance Forum (2009 & 2010)
- ACI Medical Affairs Conference (2009)

Prior Testimony

None.